A randomised controlled trial of medication management training for CPNs.

Gray, Richard John

A RANDOMISED CONTROLLED TRIAL OF MEDICATION MANAGEMENT TRAINING FOR COMMUNITY PSYCHIATRIC NURSES

Richard John Gray

Institute of Psychiatry, Kings College, London

Supervisors: Professor Kevin Gournay, Professor Til Wykes

This thesis is submitted to the University of London for the degree of

Doctor of Philosophy

To George and Emily

ACKNOWLEDGEMENTS

I am indebted to Professor Kevin Gournay and Professor Til Wykes for their help and support in undertaking this project. I am also grateful to my colleagues in the Institute (especially the statisticians) who have, without exception, always been prepared to give advice when asked. The comments on this thesis provided by Professor Anthony David. Stuart Lancashire and Morven Leese were extremely useful. I am especially grateful to Ann-Marie Parr, Susan Plummer, Melisa Edmonds, Sara Dickson, Jessica Walburn, Jane Sayer, Adrianne Reveley, and Hillary McCallion and to the CPNs and patients who participated in the trial. Thanks!

This project was funded by the Bethlem and Maudsley NHS Trust.

ABSTRACT

Non-compliance with antipsychotic medication is one of the main causes of relapse in people with psychotic illnesses such as schizophrenia. In controlled trials, medication management interventions such as compliance therapy and behavioural tailoring have been shown to be effective in enhancing adherence. Community Psychiatric Nurses (CPNs) are ideally placed to deliver such interventions but require additional training to equip them with the necessary knowledge and clinical skills.

An initial investigation, a national survey of 250 CPNs, confirmed that current medication management practice was generally poor but was enhanced if CPNs had attended psychosocial intervention training (the Thorn course). An 80 hour medication management training package was developed, based on the available literature and expert consensus opinion, and was piloted on fifteen CPNs. Following training there were significant improvements in knowledge and clinical skills suggesting that further investigation within the context of a randomised controlled trial was warranted.

A randomised controlled trial compared medication management training with routine CPN care. It was hypothesised that medication management training would lead to clinically significant improvements in patients' psychopathology, as a result of enhanced treatment compliance, compared to routine care at week 26 assessment.

Sixty CPNs were organised into geographical clusters (to minimise the risk of contamination) and randomised to either the experimental or waiting list control group.

Each CPN identified two patients on their caseload who were assessed at baseline, week 26 and week 52. The primary outcome measure was the Positive and Negative Syndrome Scale (PANSS).

Forty-four CPNs completed the trial. At the week 26 assessment, the patients of 48% of CPNs in the experimental group and 26% of CPNs in the control group showed improvements on the primary outcome measure. Response was maintained in the experimental group at the week 52 assessment. Medication management training was also superior to routine care in improving patients' attitudes towards treatment and compliance, which were clinically significant. Intention to treat analysis did not substantially alter the results of the trial.

CONTENTS

CHAPTER ONE: BACKGROUND

CHAPTER TWO: SURVEY OF CPN PRACTICE

CHAPTER THREE: DEVELOPMENT AND PILOTING OF THE MEDICATION MANAGEMENT TRAINING PROGRAMME

FIGURES

APPENDICES

CHAPTER ONE: BACKGROUND

1.1 OVERVIEW OF SCHIZOPHRENIA

Schizophrenia is a debilitating mental disorder characterised by a range of symptoms including: delusions, formal thought disorder, hallucinations, abnormal affect, passivity phenomena, motor abnormalities, cognitive deficits, lack of volition and lack of insight (WHO, 1992). The presentation of the illness varies tremendously not only between individuals but within the same individual at different stages of their illness. Schizophrenia occurs in all cultures and has a lifetime incidence of about one per-cent. The average age of onset is around 27 years in men and 31 years in women (Jones *et al.*, 1994).

A number of studies have examined the premorbid and prodromal phases of schizophrenia (Shepherd *et al.,* 1989; McGlashan, 1998; DeQuardo, 1998) and seem to highlight that patients show evidence of developing schizophrenic symptoms months or even years before they have contact with psychiatric services. In a study by Jones *et al.* (1994) prospective data were collected on 4,746 individuals born in the UK during one week in 1946. The results demonstrated subtle motor, linguistic and social dysfunction in children who later developed schizophrenia. They showed increased deviance with age, and cognitive decline became progressively more marked in early adolescence. The premorbid phase merges into the prodromal phase in which actual functional decline may be accompanied by eccentric ideas and interests, changes in affect, unusual speech and bizarre perceptual experiences.

Until recently the course of schizophrenia was considered to be one of continuous deterioration (Shepherd *et al.*, 1989). However, very few studies have followed people with schizophrenia beyond the middle decades of life. Long-term studies that have been carried out suggest that schizophrenia tends to have a prolonged course with the greatest variability in the initial stages (Bleuler, 1974; Ciompi, 1980).

The aetiology of schizophrenia is complex. Although the genetic contribution is well established (Gotesman *et al.*, 1987) other, probably environmental, factors clearly play a role. Environmental factors that have been studied include pregnancy and birth complications (Rifkin *et al.*, 1994; O'Callaghan *et al.*, 1994; McNeil, 1995), life events (Bebbington *et al.*, 1993) and family interactions (Bebbington and Kuipers, 1994).

1.2 PHARMACOLOGICAL TREATMENT OF SCHIZOPHRENIA

Antipsychotic medication has been the mainstay of treatment for schizophrenia since the 1950s when it was discovered that the dopamine antagonist's haloperidol and chlorpromazine exert antipsychotic effects. The dopamine hypothesis of schizophrenia is supported by reports that the clinical potency of antipsychotics is proportional to the extent to which they block dopamine receptors (Creese *et al.*, 1976). These observations led to the widespread belief that excessive dopamine activity or hyperdopaminergia is associated with the pathophysiology of schizophrenia.

According to the dopamine hypothesis, antipsychotic agents ameliorate the positive symptoms of schizophrenia through dopamine D_2 blockade in the mesolimbic system. In

fact, in vitro studies have shown a linear relationship between antipsychotic potency and D_2 blockade (Pilowsky *et al.*, 1992). Developments in imaging techniques such as Positron Emission Tomography (PET) and Single Photon Emission Tomography (SPET) have made it possible to carry out in vivo studies visualising receptor binding sites in the brain. One PET study showed that a relatively modest dose of haloperidol (2mg/day) resulted in 53-74% occupancy of available D_2 receptors (Farde *et al.*, 1992). This observation carries important clinical implications. It may suggest that there is a maximum effective dose, above which there is no improvement in efficacy and a possible decline in tolerability.

An inadequate response to treatment with neuroleptics may be encountered in more than 30% of patients with schizophrenia (Kane, 1989). It has been hypothesised, but not confirmed, that a poor response to antipsychotic medication is due to inadequate occupancy of central D_2 receptors. One SPET study showed no significant difference in striatal D_2 receptor availability among antipsychotic responders (n=10), antipsychotic non-responders (n=8) and normal controls (n=20) (Pilowsky *et al.*, 1993). This suggests that a poor clinical response cannot be attributed to inadequate striatal D_2 occupancy.

Other reports suggest that a high affinity for D_2 receptors may not be the only basis for efficacy in antipsychotic agents. Although these drugs typically occupy these receptors within a few hours of administration, there is often a 1-3 week delay before therapeutic benefits are reported (Gray, 1998a). This suggests that these drugs act via a series of secondary, and as yet unknown, processes that evolve over days to weeks. There are

suggestions that a number of other neuroreceptors, peptides, and amino acid systems may be involved. This is further supported by the fact that changes in systems other than the dopamine system have been implicated in the aetiology of schizophrenia these include; serotonin, glutamate, noradrenaline, neurotensin, and aminobutyric acid.

Chlorpromazine, the first effective pharmacological treatment for the symptoms of schizophrenia was introduced during the 1950s. Since then, a variety of antipsychotic agents have been developed. Controlled clinical trials have repeatedly shown that these drugs are generally efficacious for the positive symptoms of schizophrenia. However, tolerability problems, especially acute extrapyramidal symptoms (EPS; dystonias, akathisia, and Parkinsonism), encountered with these so called conventional agents has prompted further research into the development of improved novel and atypical agents such as risperidone, olanzapine, and quetiapine.

Conventional antipsychotic agents are often associated with a high incidence of extrapyramidal symptoms. In a much-cited study, Ayd (1961) surveyed 3,775 patients treated with both high and low-potency conventional antipsychotic drugs and reported that 38% of the sample developed acute EPS. However, subsequent studies have produced wide variations in the incidence of EPS. For example, the incidence of akathisia varies from 10% to 75% in different studies (Adler, 1989) and dystonia from almost zero to 90% (Casey and Keepers, 1988). The incidence of Parkinsonism is more consistently observed in approximately 50% of patients treated with conventional antipsychotics (Keepers *et al.*, 1983). Much of this variation can be explained by methodological and

diagnostic variations in study design. However, there does appear to have been a steady increase in the prevalence of acute EPS in the past 30 years. This is almost certainly due to the increased use of higher doses of high potency antipsychotics (Casey, 1996).

Although EPS are typically perceived as the most troublesome side effects associated with antipsychotic agents, other side effects are also encountered with their use. Antipsychotic agents have complex receptor binding profiles that may underlie these effects. Hyperprolactinemia, caused by dopamine blockade in the tuberoinfundibular dopamine pathway, may cause sexual dysfunction, amenoreah, galactorrohoea, or gynacomastia. The blockade of muscarinic receptor may cause anticholinergic symptoms (dry mouth, blurred vision, constipation) whilst the blockade of histamine receptors may induce sedation. Little trial evidence exists on how to manage many of these symptoms, although the management of acute EPS have been investigated in a number of studies.

1.2.1 Management of acute EPS

The treatment of acute dystonia and Parkinsonism is broadly similar and is generally treated in two ways, dose titration, or more commonly, via the addition of other pharmacological therapies. The recognition that EPS, at least in part, results from dopamine/acetycholine imbalance secondary to dopamine blockade (Borrison, 1985) has led to the widespread clinical use of anticholinergic drugs that reduce cholinergic activity or, less frequently, dopamine agonists that enhance dopamine activity. Although early studies, which were not methodologically robust, failed to confirm the superiority of anticholinergics over placebo as anti-Parkinsonian agents (Mindham, 1976). A number of

controlled studies have established the efficacy of anticholinergics in the treatment of acute Parkinsonism (Mindham *et al.*, 1977; Korsgaard and Friis, 1986) and dystonia (Goff *et al.*, 1991; Winslow *et al.*, 1986).

Although anticholinergic drugs are commonly used prophylactically to prevent the onset of EPS, the evidence for this strategy is weak. In a review of the use of anticholinergics Lavin and Rifkin (1991) found few data to support their use prophylactically, although they did conclude that in young patients receiving high potency antipsychotics such a strategy might be useful.

Anticholinergics are themselves associated with a range of side effects including dry mouth, blurred vision, constipation, tachycardia, urinary hesitancy or retention, and erectile dysfunction in men or failure of vaginal lubrication in women (Barnes and McPhillips, 1996). There are also data which suggest that anticholinergics may provoke or exacerbate tardive dyskinesia (TD) and that if withdrawn symptoms of TD improve (Chouinard *et al.*, 1988; Gerlach and Casey, 1988). Rebound phenomena, including nausea, abdominal pain, restlessness and insomnia (Gardos *et al.*, 1978; Jellinek *et al.*, 1981), and more recently akinetic depression (Bermanzohn and Stris, 1994) have been reported following the rapid cessation of anticholinergics. Drachman (1977) also observed that anticholinerics produce cognitive deficits similar to those observed in normal ageing. In a double blind study of the effects of benzatropine on cognitive functioning in people with chronic schizophrenia, Baker *et al.* (1983) found that when patients were switched to a placebo treatment their scores on tests of cognitive

functioning improved significantly. Results suggest that anticholinergics may have specific effects on patients' short-term memory and their ability to sustain attention.

Dopamine agonists, such as amantadine, restore the dopamine/acetylcholine balance and have been shown in a number of controlled trials to be as effective as anticholinergics in treating EPS (DiMascio *et al.,* 1976; Fann and Lake, 1976; Stenson *et al.,* 1976). However, whilst avoiding the side effects of anticholinergics, dopamine agonists have been shown to have their own problematic side effects including mood disturbance (Rego and Geller, 1989), exacerbation of psychotic symptoms (Nestelbaum *et al.*, 1986) and the potential to be fatal in overdose (Cook *et al.,* 1986). Perhaps as a result they are rarely used clinically.

Acute Parkinsonism and dystonia respond relatively well to treatment with anticholinergics. Akathisia, however, responds in a less than satisfactory way (Boodhoo and Sandler, 1991). In a series of studies, β-blockers (e.g. propranolol) have been shown to be effective in treating akathisia (Flischhacker, 1991; Kramer *et al.*, 1988; Yassa *et al.*, 1988). Trials have also shown that benzodiazapines are an effective treatment for akathisia (Kabes *et al.*, 1982), although their mode of action, again, remains unclear.

The evidence for the efficacy of dose titration as a strategy for managing acute EPS is also uncertain. Data from studies using Positron Emission Tomography (PET) suggest that, *in vivo*, clinical response is achieved when 50-60% of striatal D_2 receptors are blocked, but EPS only emerges when >80% are blocked (Nordstrom *et al.,* 1993). This

suggests that a reduction in the dose of an antipsychotic to within this therapeutic window of D_2 blockade should minimise acute EPS. This hypothesis has not, however, been tested in large-scale clinical trials.

1.2.2 Atypical antipsychotics

Perhaps the most effective way of minimising the risk of EPS is via the use of atypical or novel antipsychotics that, by definition, have a low propensity to induce EPS. The early 1990s saw the introduction of clozapine the first of a new generation of antipsychotic drugs. However, clozapine is not a new drug. When it was first introduced into Europe during the 1970s it was met with great hope. This drug overcame many of the limitations of the conventional neuroleptics in that it appeared to reduce negative symptoms, it was associated with little or no EPS, and it was effective for patients with refractory illness. However, in 1975 agranulocytosis developed in 18 of 3,200 clozapine-treated patients in Finland, and 4 of 2,900 in Switzerland (Gray, 1998a). The serious nature of this side effect led to the voluntary withdrawal of clozapine from the market. Nonetheless, the advent of clozapine marked an important advance in the treatment of schizophrenia.

In 1988, results of a multicentre study revealed that clozapine was more effective than conventional neuroleptics for patients with treatment-resistant schizophrenia (Kane, 1988). A number of controlled (Claghorn *et al.*, 1987) and uncontrolled (Meltzer, 1989; Matted, 1989; Owen *et al.*, 1989; Clozapine Study Group, 1993) studies have demonstrated that clozapine is a clinically useful drug that reduces both the positive and negative symptoms of schizophrenia with a low incidence of EPS. In 1990, it was

introduced in the U.K. with strict guidelines for haematological monitoring because of the associated risk for agranulocytosis. Clinical experience with clozapine has led to the development of other novel antipsychotic agents including risperidone, olanzapine, sertindole, quetiapine and ziprasidone.

Phase III and IV clinical trials of these agents have repeatedly shown that they have placebo levels of EPS (around 7-16%; Gray, 1999). However, there is a great deal of variability in the mode of action of these drugs. For example, risperidone and ziprasidone are potent dopamine D_2 and serotonin 5-HT_{2a} antagonists, whilst clozapine, olanzapine and quetiapine are multireceptor antagonists (Moore, 1999).

In practice, because of their classical affinity for dopamine D_2 receptors, risperidone and ziprasidone will, at high doses, induce EPS. The same is not true of clozapine, olanzapine and quetiapine which have a much weaker affinity for D_2 receptors and as a result do not have the propensity to induce EPS at higher doses (Bigliani and Pilowsky, 1999). It has been proposed, but not confirmed, that risperidone and ziprasidone have a low incidence of EPS because of serotonin-dopamine interactions in the basal ganglia. Serotonin blockade appears to reverse the effects of dopamine D_2 blockade, but only in the nigrostriatal system and not in the mesolimbic system (Kapur and Remington, 1996). Clozapine, olanzapine, and quetiapine in contrast appear to have a naturally high affinity for dopamine receptors in the mesolimbic system (Bigliani *et al.,* 1998) and consequently a low propensity to induce EPS.

There is convincing evidence for the efficacy of conventional antipsychotics. However, they may tend to be used in higher than necessary doses and are generally poorly tolerated. There are few data to assist in the management of many of these symptoms and the evidence suggests that the management of acute EPS is challenging. Novel and atypical antipsychotics are generally very well tolerated and have a low propensity to induce many of the problematic side effects associated with conventional treatments (Gray *et al.*, 1999). Guidelines have been published to guide clinicians on how to effectively use antipsychotics and minimise side effects (Taylor *et al.*, 1999) although concern has been repeatedly expressed that clinicians fail to follow such guidance.

1.3 THE PROBLEM OF NON-COMPLIANCE

There is good evidence that the prophylactic use of antipsychotic medication reduces the risk of relapse (Marder *et al.,* 1999; Kane 1989). However, a number of studies have demonstrated that compliance with antipsychotic medication is generally poor and not taking medication is associated with a substantial increase in relapse rates, more frequent hospitalisations and a generally poorer outcome in people with psychotic illnesses (Gabel and Piezcker, 1985; Helgason, 1990). Kemp *et al.* (1997) have proposed that the so called 'revolving door phenomena' can be almost exclusively attributed to repeated non-compliance. Kisling (1994) has argued that if patients were completely compliant with their medication, relapse rates would fall to about 15% (currently 50% of patients relapse within a year of achieving remission). However, the assumption that poor compliance can be attributed solely to the patient's failure to do what clinicians have told them to must be juxtaposed with evidence that professionals often do not carry out their own

responsibilities regarding medication. For example, Taylor *et al.* (2000) showed that prescriptions for antipsychotics are often inappropriate resulting in unwanted and unnecessary side effects.

It has been proposed that either 'concordance' or 'adherence' should replace the use of the word 'compliance'. Concordance emphases patient rights, the need for information and the importance of two-way communication and decision making (although, this has to be considered in light of the cognitive deficits and behavioural problems that are common in people with schizophrenia). However, it is clinicians' practice rather than the language that they use that is important, and it is practice that is the focus of this thesis.

1.3.1 How common is non-compliance?

Estimating compliance rates in people with schizophrenia has proved difficult for two reasons. Firstly, there is no agreed definition of compliance - definitions vary from complete cessation or verbal refusal, to any significant deviation from prescription, including dosage errors or failure to attend appointments. Secondly, there is no valid way of measuring compliance. Rates of compliance have been measured using a number of different methods none has proved satisfactory. These include physicians' assessment and patients' self-report, pill counts, and urine and blood assays. These methods of assessment are not always reliable. Patient self-report and physician assessment are inaccurate, both consistently overestimating compliance (Churchill, 1985). Pill counts are more reliable, but it is impossible to tell whether the patient has actually ingested the medication. Urine testing for a drug with a long half-life will tend to overestimate

compliance. Since most neuroleptics have a relatively long half-life, blood assay is likely to prove more reliable. However, the degree of compliance is impossible to determine and therefore blood assays can only be used as a criterion for current compliance (Babiker, 1986).

The problem of accurately measuring adherence explains inconsistencies in the incidence of non-compliance reported in people with schizophrenia. For example, Quitkin *et al.* (1978) used clinician judgement to determine compliance and observed that only 10% of patients were non-compliant with their medication over a twelve month period. In contrast Wolff and Colacino (1961) using patient interview over a six-month period reported that 73% of patients were non-compliant. However, in a review of the world literature Cramer and Rosenheck (1998) proposed an average non-compliance rate of approximately 42% a finding that is similar to rates in other mental and physical disorders.

1.3.2 Why are patients non-compliant?

Difficulties in reliably measuring compliance not only make it challenging to quantify the incidence but also to produce a model to explain how patients make decisions about taking antipsychotic medication. Studies have attempted to identify factors that affect compliance, but are characterised by serious methodological problems over and above the measurement of compliance.

- Several of the studies reviewed divide patients into two groups, compliant or non-compliant, even though compliance is often partial rather than an all-or-nothing phenomenon (Cramer and Rosenheck, 1998).
- There is a risk that the assessment procedure itself may influence the behaviour under investigation. Poor adherence tends to disappear under scrutiny and the findings are therefore likely to reflect recent rather than overall compliance (Blackwell, 1996).
- It is difficult to ensure the participation of all patients in a given population. By definition, non-compliant patients may not want to participate in a research project.

Given these limitations, what factors influence compliance in people with schizophrenia? Patients with a physical disorder who accept that they have an illness and perceive it as serious ('are insightful') tend to be more compliant (Haynes, 1976). This is consistent with the Health Belief Model, which hypothesises that individuals reach decisions on health actions based on their perception of the seriousness of the illness, their susceptibility to it and the benefits of adherence (Babiker, 1986). In studies of non-psychiatric patients this model generally shows a modest ability to predict/explain treatment compliance (Meichenbaum and Tusk, 1987).

In schizophrenia, insight - defined as, awareness of illness, an ability to recognise symptoms as part of an illness and acceptance of treatment - has also been associated with compliance. A number of studies have examined the relationship between insight and compliance with generally consistent results, despite substantive differences in operational definitions of insight. Lin *et al.* (1979) showed a significant relationship

between insight and compliance in a prospective study. Marder (1983), Buchanan (1992) and Kemp and David (1996) have all produced similar results. Some contradictory findings have, however, been reported (McEvoy *et al.*, 1989).

A number of interpersonal (such as the therapist's ability to listen and empathise with the patient) and relationship factors (liking and trusting the therapist; and the patient's level of involvement in treatment decisions including discussion of the patient's beliefs, concerns and expectations) have been shown to correlate with compliance in patients with physical disorders (Haynes, 1976). Patient interactions with the therapist, including the process of formulating perceptions, therapist-influence and the patient's evaluation of the treatment are incorporated into the 'Theory of Reasoned Action' (Cochran and Gitlin, 1988). However, the ability of this model to explain or predict compliance has not been tested.

Psychotic psychopathology, especially paranoia, suspiciousness, grandiosity and delusional beliefs about medication, were highlighted as influencing compliance in a study by Appelbaum and Gutheil (1980) who interviewed 40 patients who refused antipsychotic medication during a three month period. Similar results were reported by van Putten *et al.* (1976) and Bartko *et al.* (1988) who both observed that grandiose delusions were more common in non-compliant patients. The more severe a patient's psychopathology the worse their compliance. Renton *et al.* (1963) examined this relationship in a study of 132 patients. They reported that the severity of patients' symptoms at the time of discharge was significantly associated with future adherence.

Two studies have shown that when asked, patients indicate that, subjectively, side effects have a significant impact on compliance (Weiden *et al.*, 1986; Renton *et al.*, 1963). However, when this is examined more objectively findings are equivocal. Mutsatsa *et al.* (under review), for example, showed that contemporaneous side effects had a weak but significant impact on compliance. van Putten *et al.* (1974) demonstrated an increased incidence of bradykinesia, dystonia and tremor, but not akathisia, in patients who were reluctant to take medication. In this study akathisia was not associated with non-compliance probably because of the difficulty in distinguishing it from anxiety. In a further prospective study a strong correlation between akathisia and compliance was found (van Putten *et al.*, 1984). However, these findings have not been consistently replicated. In a two-year prospective study Buchanan (1992) found no correlation between akathisia and compliance although the study only examined side effects reported at discharge from hospital. Flischhacker *et al.* (1994) also failed to establish a link between EPS and compliance in patients receiving long-term treatment with either clozapine or haloperidol. Non-compliance with either drug was not predicted by the incidence of Parkinsonian symptoms or akathisia during the first four weeks of treatment.

There is some evidence that a number of other factors may influence compliance: McEvoy *et al.* (1989) suggested that compliance was substantially higher in patients whose medication was supervised by a family member; Swofford *et al.* (1996) found that compliance rates were much lower in patients with a co-morbid substance misuse diagnosis. Other factors that are suggested within the literature as affecting compliance

but lack any empirical evidence include the complexity of treatment regimes (Parkin *et al.*, 1976), and the patient's sociocultural background (Piatkowska and Farnill, 1992).

1.3.3 Factors that enhance compliance

Adams and Howe (1993) examined factors that were likely to predict good compliance in 44 psychotic inpatients. The greater the number of indirect benefits of medication (i.e. "keeps me out of hospital" or "it allows me to make new friends"), the more compliant patients were. Similar results were reported by Chan (1984) who observed that compliant patients had generally derived positive benefits from medication.

These data suggest that a number of pragmatic interventions may be potentially useful in improving compliance, and consequently the health, of people with schizophrenia.

1.4 INTERVENTIONS TO ENHANCE COMPLIANCE

Given the relationship between good compliance and outcome it is perhaps surprising how little research effort has been devoted to devising and testing interventions to improve the taking of prescribed antipsychotic medication. A range of interventions has been evaluated in patients with both physical and mental disorders although much of the research has focused on schizophrenia or acute psychosis. The interventions that have been tested include patient education (Seltzer *et al.*, 1980; Stricker *et al.*, 1986; Brown *et al.*, 1987; Smith *et al.*, 1992; Macpherson *et al.*, 1996a; Gray, 2000), behavioural interventions (Boczkowski *et al.*, 1985) and cognitive behavioural interventions (Hayward *et al.*, 1995; Lecompte and Plec, 1996; Kemp *et al.*, 1996; 1998). Although the

number of patients in these studies was generally quite small, statistically significant increases in medication adherence were found following some of the interventions. Very few of the trials reported the impact of the intervention on clinical outcomes. Because of the small sample sizes in these studies, the possibility of a false-negative (type II) error is quite high.

1.4.1 Educational interventions

Educational interventions aim to provide information to patients about both their illness and medication with the goal of increasing understanding and promoting compliance. Group and individual patient education has been evaluated using a variety of methodologies including a number of randomised controlled trials.

Group educational interventions were tested by Stricker *et al.* (1986) and Smith *et al.* (1992). The curriculum for the Stricker *et al.* (1986) medication education groups was divided into two parts. The first part consisted of six, weekly, didactic presentations about the major drugs used in psychiatry, the risks associated with substance misuse and the biochemical theory of schizophrenia. During the second part, over a four-week period, weekly discussions took place about the importance of taking medication, communication with physicians, and the benefits of long-term medication adherence. The groups were large with up to fifteen patients attending each.

The groups were evaluated by randomly assigning 75 chronic psychiatric patients to receive either the educational package or standard care. Patients were then assessed

before and after attending the educational groups and at 35 week follow-up using three measures developed specifically for the study; a self report attitudes towards treatment questionnaire, a multiple choice knowledge questionnaire, and a dichotomous observer rating of compliance. Although the authors stated that these measures had been tested for validity and reliability these data were not reported.

At follow up no difference in compliance or attitudes towards treatment were observed between the experimental and control groups. However, significant improvements in patients' knowledge were observed between the groups at post-treatment assessment and at follow-up. Patients also reported a high degree of satisfaction with the intervention.

In a study examining the effect of residual psychotic symptoms on knowledge acquisition by people with schizophrenia, Smith *et al.* (1992) evaluated a group educational intervention based on material developed for family psychoeducation (Smith and Birchwood, 1992). The intervention was delivered fortnightly over an eight-week period. The concept, symptoms and treatment of schizophrenia, in addition to basic symptom management strategies were discussed with small groups of patients (5-6 per group) in four fortnightly sessions. A booklet backed up the information presented in the groups.

Twenty-eight patients were divided into two groups, those with and those without residual positive symptomatology, whom both received the same educational intervention. Patients were assessed prior to and immediately after, the educational intervention using valid measures of knowledge, insight, and compliance. It was not

reported whether the researcher who was collecting the data was blind to the treatment condition. Findings were similar to those reported by Stricker *et al.* (1986), no significant improvement in patients' compliance or insight was observed in either group, though both groups showed an increase in knowledge about their medication. The authors observed that although significant improvements in knowledge were found in both groups, patients who had no residual symptoms absorbed more information than those who were still symptomatic.

Both of these studies suggest that whilst educational interventions are effective in improving patients' knowledge they have little impact on compliance with medication. One explanation for this finding may be that group interventions are not the most effective method of providing patients with information about their treatment. Macpherson *et al.* (1996a), Brown *et al.* (1987), Gray (2000) and Seltzer *et al.* (1980) all examined whether individual patient education was effective in improving compliance with medication. The intervention devised by Macpherson *et al.* (1996a) consisted of either one or three individual sessions of education about medication. All sessions were individually tailored around an information booklet that was derived from the psychoeducation literature (Smith and Birchwood, 1987).

Sixty-four patients were randomised to receive either one session or three sessions of patient education or standard care. They were assessed by the clinician who delivered the intervention, using a battery of standardised valid measures, including the Positive and Negative Syndrome Scale (PANSS Kay *et al.*, 1989a) and the Schedule for the

Assessment of Insight (SAI, David, 1990). The Understanding of Medication Questionnaire (UMQ), a measure of patients knowledge about treatment was developed specifically for the study and validity and reliability data are reported in a separate paper (Macpherson *et al.*, 1996b). Compliance was determined using a single item sub-scale of the SAI. These were administered at baseline, immediately post intervention (or after four weeks in the control group), and at eight-week follow up.

Again, patient knowledge about medication improved immediately after both the one and three sessions of education. However, at follow up, three sessions of education were significantly superior to one session. As in the study by Strickner *et al.* (1986) and Smith *et al.* (1992), compliance did not improve post-intervention or at follow up, in any group. However, in contrast to Smith *et al.* (1992) insight was enhanced in patients who received three, but not one, sessions of education.

Individual patient education was also examined by Brown *et al.* (1987) who randomly assigned 30 patients to receive one of four treatment conditions: verbal information about their medication but not about side effects; verbal and written information about their medication but not about side effects; verbal information about medication and about side effects; or verbal and written information about medication and side effects. A psychiatrist, who was not blind to the treatment condition, assessed patients on a monthly basis for four months using measures of knowledge, side effects and compliance. Compliance was measured using pill counts, patient self-report, and observer rating.

Again patient education improved patients' knowledge about their medication but failed to enhance compliance.

Gray (2000) examined the effect of three sessions of structured patient education in a randomised controlled trial of 44 patients with schizophrenia taking clozapine. Once again the intervention had no effect on patients' insight into their illness or their attitudes towards treatment.

Although limited by some methodological considerations, most notably assessment of patients by assessors who were not blind to the treatment condition, the evidence from studies evaluating both group and individual educational interventions seems to suggest that whilst they are effective in improving patients' understanding of their treatment they are not effective in enhancing compliance with medication. However, confounding data have been reported by Seltzer *et al.* (1980).

Sixty-seven inpatients were divided, but not randomised, into experimental and control groups. The experimental group received 9 lecture and discussion sessions about the nature of mental disorder and its pharmacological management. Within these sessions specific attention was given to drawing a link between relapse and stopping medication. At discharge patients were given written drug information. The control group received standard care.

Patients were assessed at baseline and at five-month follow up by an independent, but not blind, assessor. Compliance was assessed using pill-counts and FPN phenothiazaine urine tests - both measures of current, not long-term, compliance. Patients' knowledge about, and attitudes towards, medication were determined using a 14 item scale developed specifically for the study. At follow up, patients in the experimental group were significantly more compliant than those in the control. However, compliance data for more than half of the patients in the study were missing at follow up which casts severe doubt on the validity of the findings.

Although Seltzer *et al.* (1980) provide some confounding data, this was flawed because compliance was assessed in so few patients at follow up. It is therefore reasonable to conclude that simple educational interventions, whilst effective in improving patients' knowledge about medication, are generally not effective in enhancing compliance.

1.4.2 Behavioural interventions

If improving patients' understanding about their medication does not improve adherence then interventions may need to address some of the other factors that influence compliance. Boczkowski *et al.* (1985) hypothesised that helping patients to tailor their medication so that it fitted in with their daily routine would be effective in enhancing compliance. This was evaluated in a controlled trial of 36 patients who were randomly assigned to receive one session, lasting up to 50 minutes, of either behavioural tailoring, psychoeducation or a control intervention. Patients were assessed pre-intervention and at one month and three month follow-up. Patients' knowledge and attitudes were

determined using a self-report scale. Compliance was determined using pill counts and ratings from patients and carers.

Patients who received the behavioural tailoring intervention were informed of the importance of taking their medication. They were also encouraged to link taking medication with specific routine behaviours (e.g. making breakfast, turning off the television at night). Patients were also given a calendar with a dated slip of paper for each dose of antipsychotic. Patients were told to keep the calendar with the medication and remove the appropriate strip when they took their medication. The educational intervention was similar to that describe by Seltzer *et al.* (1980), and the control intervention focused on themes not related to medication or diagnosis.

The evidence that behavioural tailoring was effective in enhancing compliance is inconclusive. Compliance, as measured by pill count, was significantly improved in patients who received behavioural tailoring compared to either of the control interventions. However, compliance measured using patient and observer self-report did not improve. This suggests that either self-report was inaccurate or patients had learned to adjust the number of tablets returned for the purposes of pill counting to falsely demonstrate improved compliance.

1.4.3 Cognitive-Behavioural Interventions

Whilst behavioural tailoring attempts to address some of the factors affecting compliance, patients' reasons for not taking their medication are diverse. Several studies have

examined the use of cognitive behavioural interventions to involve patients in their treatment and encourage them to examine the range of factors affecting compliance (Lecompte and Pelc, 1996; Hayward *et al.*, 1995; Kemp *et al.*, 1996; 1998).

Lecompte and Pelc (1996) tested a cognitive behavioural programme based around five therapeutic strategies: engagement; psychoeducation; identifying prodromal symptoms and developing coping strategies; behavioural strategies for reinforcing compliant behaviour; and correcting false beliefs about medication. Sixty-four non-compliant psychotic patients were randomly assigned to receive either the cognitive behavioural intervention or a control intervention (unstructured conversation). The duration of the intervention is not reported.

The duration of hospitalisation one year before and one year after the intervention was reported as an indirect measure of compliance that was not directly observed. Patients who received the cognitive behavioural intervention spent significantly less time in hospital than those in the control group. However, it is unclear whether this improvement can be attributed to improved compliance or to other factors such as increased use of coping strategies.

A more robust evaluation of a cognitive behavioural intervention is described by Hayward *et al.* (1995). Medication self-management was based on motivational interviewing and aimed to allow patients and clinicians to work collaboratively to examine medication issues.

Twenty–one patients were randomly assigned to receive three 30 minute sessions of either medication self-management or a control intervention (non-directive discussion on any issue except medication). Patients were assessed pre- and post-intervention using measures of attitude toward medication, insight and psychopathology. The doctor in charge of the patient's outpatient treatment rated compliance on a three-point scale ranging from 1 (totally non-compliant) to 3 (good compliance). Although differences between groups in insight, attitude toward treatment, and compliance were observed, none reached statistical significance. This may, in part, be because of the small number of patients in the study, the short duration of the intervention, and an unsophisticated measure of compliance. However, the pilot work led to the development of a longer more structured intervention, compliance therapy.

Kemp *et al.* (1996; 1998) devised compliance therapy based on motivational interviewing and cognitive behavioural techniques. Key principles include working collaboratively, emphasising personal choice and responsibility, and focusing on patients' concerns about treatment. The intervention was divided into three phases which acknowledges that readiness to change is on a continuum. Phase 1 deals with patients' experiences of treatment by helping them review their illness history. In phase 2 the common concerns about treatment are discussed and the good and the bad things about treatment are explored. Phase 3 deals with long-term prevention and strategies for avoiding relapse.

The intervention was evaluated in a large-scale randomised controlled trial (Kemp *et al.*. 1996; Kemp *et al.*, 1998). Seventy-four psychotic inpatients were randomly assigned to receive either compliance therapy or non-specific counselling. Patients received 4-6 sessions with a research psychiatrist lasting, on average, 40 minutes and were assessed at baseline, post-treatment and three, six, twelve, and eighteen month follow-up, using a battery of standardised measures, including an observer rated measure of compliance. Although an assessor blind to the treatment condition performed the latter assessments the person conducting the therapy undertook the initial interviews. Treatment adherence was significantly better in the compliance therapy group and was sustained through follow-up. Unexpectedly, there was no significant difference in psychopathology between the groups. However, the improvements in compliance did result in enhanced community tenure, with patients in the compliance therapy group taking longer to relapse than those who received non-specific counselling.

1.4.4 Implications for clinical practice

Non-compliance with antipsychotic medication is clearly a major preventable cause of relapse in patients with psychotic disorders. The causes of non-compliance are unclear but the evidence does suggest that a number of factors have a role to play and that individuals reasons for stopping medication are idiosyncratic. A range of different pragmatic interventions to enhance compliance have been tested. However, many lack sufficient methodological rigor: none offered any statistical justification for their sample size; raters were often not blind to the treatment condition; there was an unnecessary reliance on specially developed measures; and therapist time was often not controlled for.

Based on the available evidence, medication management aimed at enhancing treatment concordance should consist of the following:

- A collaborative approach to working with patients.
- Use of valid and reliable assessment tools to measure psychopathology, antipsychotic side effects, attitudes towards treatment, insight and compliance.
- Giving patients information about their illness and treatment.
- Tailoring medication regimes to suit the patient.
- Use of compliance therapy techniques.

1.5 MEDICATION MANAGEMENT PRACTICE IN THE BRITISH NATIONAL HEALTH SERVICE

Standards four and five of the National Service Framework for mental health (Department of Health, 1999) aim to ensure that people with severe mental illnesses receive care and treatment that has a sound empirical basis. Good medication management, as described above and including the use of rigorous assessments with valid and reliable measures and the application of compliance therapy techniques, is clearly identified within the framework as being integral to achieving these standards.

Much of the care and treatment that people with schizophrenia receive is delivered by Community Psychiatric Nurses (CPNs). The most recent national survey reported that in 1996 there were approximately 6,700 CPNs working in England and Wales treating

around 49% (122,723) of the patients with serious mental disorders (Brooker and White, 1997).

Brooker and White (1997) reported that CPNs were generally experienced nurses employed on a senior grade and spent almost 50% of their time in direct face to face contact with patients. On average they carried a caseload of 38 patients of which half had a serious mental disorder and 21% were receiving long acting depot antipsychotic medication. CPNs tended to specialise in using counselling or psychodynamic therapy. A minority (15.9%) of CPNs surveyed reported that they specialised in the use of psychosocial interventions that would include the application of cognitive behavioural techniques such as compliance therapy. The Brooker and White (1997) survey suggests that CPNs may play a substantive role in helping patients to manage their medication. However, it is unclear whether current practice is adequate to achieve the standards set out in the National Service Framework (Department of Health, 1999).

There are no data that directly examine the way in which CPNs promote compliance in their patients. The evidence that does exist seems to suggest that routine CPN practice relies on the unsophisticated use of basic counselling skills and not the application of more technical skills such as those used within compliance therapy. For example, in a randomised controlled trial of patients with predominantly neurotic disorders allocated to either treatment by a CPN or standard GP care there were no differences in outcomes between the groups (Gournay and Brooking, 1994). Gournay and Brooking (1994) suggest that these results can be explained by a lack of clinical skills among CPNs.

Devane *et al.* (1998) seem to support this conclusion. They demonstrated, in a study examining tape recorded CPN sessions, that although general clinical skills were satisfactory their ability to apply more complex technical cognitive therapy techniques was poor.

As has already been discussed, part of good medication management is the rigorous assessment of psychopathology, side effects and subjective factors such as beliefs about treatment and insight. CPNs practice, especially in the assessment of side effects has been explored. For example, in a small survey of CPNs practice Bennett *et al.* (1995) observed that on average CPNs screened patients for only 3-4 of the possible side effects they might experience and there was no evidence of assessment using techniques other than unstructured self-report. Gray (1998b) observed that CPNs do not ask patients about certain side effects, such as sexual dysfunction, that may have a substantial impact on patients' decisions about taking medication. There are no published data on CPNs practice in assessing psychopathology, beliefs about treatment, and insight, which are part of a good medication management assessment.

Examining the impact of using valid and reliable assessment tools on the detection of EPS Wieden *et al.* (1987) demonstrated that clinicians trained in using such measures were significantly more accurate at detecting side effects than clinicians in routine practice. There are, however, no published data on the use of such measures by CPNs in the NHS.

Although research evidence describing current CPN practice is weak, it seems reasonable to propose that routine care in terms of medication management, is inadequate to meet the high standards established by the National Service framework. These findings may be explained by the relatively small amount of time that CPNs spend in staff development and training. In the Brooker and White (1997) survey clinical supervision was provided to 87% of respondents. However, only 2% of CPNs had received any substantive training in using psychosocial interventions (which would include the use of side effect assessment tools) and only 36% had received any additional education to prepare them for working in the community.

1.6 THE EFFICACY OF CPN TRAINING

Training CPNs to use medication management techniques including the use of valid and reliable measures and compliance therapy may be one way of utilising CPNs more effectively and achieving the standards set out in the NSF. There has only been one published medication management training study (Bennett *et al.*, 1995). A number of studies have explored the impact on patients' clinical outcomes of training nurses in more sophisticated psychological interventions including: cognitive behavioural therapy (Marks *et al.*, 1977); schizophrenia family work (Brooker *et al.*, 1992a; 1994); psychosocial interventions (Lancashire *et al.*, under review); and the management of violence (Whittington and Wykes, 1996). The duration of the training varied considerably from one-day workshops (Whittington and Wykes, 1996) to 18-month full-time academic courses (Marks *et al.*, 1977).

Marks *et al.* (1977) were the first to demonstrate that mental health nurses could be trained to deliver complex cognitive behavioural interventions initially for patients with neurotic disorders. The intensive, full-time, training programme (English National Board ENB-650 behavioural psychotherapy) lasted for eighteen months and centred around a behavioural treatment rationale and the extensive use of closed circuit television (CCT) to monitor therapy sessions and provide trainees with detailed feedback on the development of their clinical skills. There is good evidence that the nurses who had received training produced good clinical outcomes in the patients they were treating (Marks *et al.*, 1977). A twenty-five year follow-up survey of the 274 nurse therapists trained in using these techniques (Gournay *et al.,* 2000) found that trainees reported a high degree of fidelity to the behavioural techniques they were taught to use during the course. However, such a programme is expensive and time consuming and is therefore impractical as a model for enhancing the practice of the 6,700 CPNs currently working in England and Wales. Shorter, and therefore more cost effective, models for disseminating psychosocial interventions needed to be developed, building on the teaching techniques that have been shown to be effective.

Brooker and Butterworth (1993) examined whether a short 26 week day release course delivered over a six month period would be effective in enhancing psychosocial intervention skills, specifically in working with families, in a cohort of nine CPNs. The course focused on the acquisition of specific clinical skills, including engagement with the family, family education, and problem solving, which were taught using role-play. CPNs were also trained to perform a series of standardised assessments and submitted

audiotapes of sessions with families for clinical supervision. The blind rating (using the cognitive therapy scale; Vallis *et al.*, 1986) of tapes submitted at the end of the course suggested that CPNs were able to demonstrate competent skills in delivering psychosocial interventions to families. However, as no baseline scores are reported the level of improvements in skills, if any, cannot be established. Published in two parts, a quasi-experimental study describing the impact of this model of training on clinical outcomes was reported by Brooker *et al.* (1992a) and Brooker *et al.* (1992b). Nine CPNs received training and each identified a partner CPN to act as a control. The CPNs in the control group were trained to administer the assessments but not the family work intervention. Forty-seven families entered the study and were allocated to either the experimental (n=17) or control (n=13) condition depending on the geographical location of their home. Data were only reported on the thirty who completed the trial. Patients and families were assessed pre-training, post-training and at six month follow-up by the CPNs treating them using a battery of valid and reliable outcome measures.

Brooker *et al.* (1992a) reported that based on CPN ratings of the Knowledge about Schizophrenia Interview (KASI; Barrowclough *et al.,* 1987) there was a significant improvement in families understanding of the illness in the experimental but not the control group. Significant improvements in psychopathology and, to a lesser extent, social functioning were also reported (Brooker *et al.,* 1992b) in patients treated by CPNs trained in family work compared to those treated by CPNs delivering standard care. However, the findings of both studies may be confounded by the use of the trainees, who were not blind to the treatment condition, to collect data. Although the findings of this

study have been replicated by Brooker *et al.* (1994), this second quasi-experimental trial had many of the methodological weaknesses of the original trial.

Lancashire *et al.* (under review) reported the results of a multi-centre uncontrolled trial to evaluate the impact of training professional mental health workers to deliver psychosocial interventions such as family work and cognitive behavioural therapy. The programme, that included a medication management component, was commonly referred to as the Thorn course after Sir Jules Thorn who funded the development of the training. Sixty-four trainees were selected following a screening interview, to receive 40 days classroom training over a single academic year and engage in an equivalent number of days clinical practice with a minimum of four patients with psychotic illnesses. Training was divided into three modules: problem orientated case management, family work and cognitive behavioural interventions for psychosis. To ensure acquisition of the skills necessary to implement the psychosocial treatments, trainees were given a clear treatment rationale, participated in weekly group supervision of their clinical work, engaged in role play exercises to rehearse skills prior to use, and audiotaped their treatment sessions for review by course tutors. Patient outcomes were determined by asking each mental health worker to identify at least two patients on their caseload who were assessed by independent evaluators pre-training and at twelve month follow-up. One-hundred and twenty patients consented to participate in the trial and significant improvements in patients' psychopathology and social functioning were observed at follow-up. Partly because of the success of this study Thorn training has become one of the major training initiative for CPNs. However, because the design of the trial was naturalistic and not

controlled it is difficult to attribute the gains observed to the application of psychosocial interventions by trainees, rather than improvements that would have occurred naturally over time.

There is also some evidence that short courses, which are targeted at specific needs, can be beneficial. For example Bennett *et al.* (1995), in the only study evaluating a medication management training intervention, showed a significant increase in the detection rates of antipsychotic side effects following a brief one day training session in which CPNs learned to use a specific side effect rating scale. Similarly, Whittington and Wykes (1996) demonstrated a substantial reduction in the number of violent incidents experienced by those who had received management of violence training compared with those who had not attended training.

The training interventions that have been tested, and shown to be effective, all rely on the presentation of an intervention with a good evidence base followed by rehearsal *in vitro* using role play of skills prior to putting them into practice. Such techniques may be effective in enhancing the medication management practice of CPNs and ultimately improving patients' mental health. Surprisingly, there appears to be little association between the duration and outcome of training. However, longer courses are obviously more expensive and perhaps therefore do not lend themselves to the rapid dissemination of interventions into routine clinical practice throughout the NHS. Pragmatically therefore, any medication management training initiative targeted at CPNs must be brief.

1.7 MEDICATION MANAGEMENT: UNANSWERED QUESTIONS

Although the quality of the data are far from satisfactory the key components of good medication management seem clear. However, there are a number of important, and as yet unanswered, questions that have emerged from the literature.

- To what extent do CPNs see medication management as part of their role?
- Do CPNs utilise recognised valid and reliable medication management outcome measures in their routine practice?
- Have recent training initiatives, such as Thorn, improved medication management practice?

These questions will be addressed in chapter two. If there are apparent deficits in current practice it would be useful to develop a pragmatic brief training intervention to address these needs. Chapter three will therefore address whether a medication management course can be effective in enhancing CPNs' skills and knowledge in this area?

However the most important question to answer is whether such training would lead to improvements in patients' psychopathology and compliance with antipsychotic medication? This is the most complex question to answer and will be the main emphasis of this thesis.

CHAPTER TWO: SURVEY OF CPN PRACTICE

2.1 BACKGROUND

As has already been established it is unclear whether CPNs are receptive to becoming more involved in helping patients manage their medication and to what extent recent training initiatives, such as Thorn, have addressed the poor practice that is alluded to within the literature. A number of important questions need to be addressed.

Do trained and untrained CPNs:

1. Indicate that medication management is part of their role?
2. Believe that they have been adequately trained to deliver medication management interventions?
3. Routinely and comprehensively assess patients for antipsychotic side effects?
4. Utilise valid and reliable measures to evaluate pharmacological interventions?
5. Demonstrate adequate knowledge about psychopharmacology and the management of antipsychotic side effects?

2.2 METHOD

2.2.1 Power calculation

A power calculation was performed to determine the number of CPNs that would need to be surveyed to detect the proportion who utilise standardised antipsychotic side effect scales in clinical practice. Assuming a population of 6,700 CPNs (Brooker and White, 1997) and that an estimated 40% use at least one recognised assessment tool (Gray, 1998b) a sample of 91 CPNs would be necessary to achieve a confidence level of 95%.

Assuming a non-response rate of 40-60% a survey sample size of 240 was estimated as likely to meet the requirements of the power calculation.

2.2.2 Sample selection

As no comprehensive national database of CPNs working in the UK exists, the sample for this study was generated using two different methods. Thorn graduates were identified by contacting the course leaders in both London and Manchester to request a list of the names and addresses of all trainees who had successfully completed training. CPNs were identified by inviting six representative urban and rural NHS Trusts in England, where Thorn training was not currently provided, to participate. Those Trusts who agreed to take part provided a list of CPNs currently in clinical practice. From these lists of 227 CPNs and 246 Thorn graduates the sample was selected. Each nurse was allocated a number, which was then sorted into a random order. The first 120 nurses in each group (total 240) were then selected and sent a brief questionnaire to complete and return.

2.2.3 Questionnaire (Appendix 1)

A 38-item questionnaire was developed based on previous research (Bennett *et al.*, 1995) and consultation with a group of clinical and academic experts. The questionnaire, which was intended to be brief and easy to complete, was designed to elicit information about practitioner demographics, caseload composition, use of assessment tools, knowledge about psychopharmacology and perceived training requirements.

Information about the composition of caseloads was obtained by asking CPNs to calculate the proportion of their patients who were suffering from different disorders. Respondents were also asked to list all the assessment tools they regularly used in their clinical practice. Knowledge about psychopharmacology was determined by asking respondents to give an *agree, disagree,* or *unsure* response to nine statements about psychopharmacology. A score of 2 was given for a correct answer, 1 for unsure, and 0 for an incorrect answer. Producing a total score ranging from 0-18. The expert group paid considerable attention to devising a list of questions that a CPN should ideally be able to answer given appropriate training. This method of examining knowledge has been used before and has been shown to be reliable and easy to administer (Gamble *et al.*, 1994).

The questionnaire was piloted on a cohort of 58 CPNs (Gray, 1998b) and the analysis of these responses allowed the questionnaire to be further refined, by removing unnecessary items and rephrasing certain questions.

Questionnaires were sent out in November 1998, together with a covering letter explaining the nature and purpose of the study. A reminder letter was sent eight weeks later if CPNs had not responded. Respondents were asked to sign and return a consent form with the questionnaire. If written consent was not obtained questionnaires were excluded from the study.

2.2.4 Statistics

Data were analysed using SPSS for windows, version 8.0. To identify between group differences independent sample t-tests were used with two-tailed significance as the most conservative method of analysis. The chi-square test (χ^2) was used to test for association.

2.3 RESULTS

2.3.1 Response rates and non-response bias

Of the 240 questionnaires that were sent out 144 (60%) were returned. Of these 30 were invalid because respondents either had never or were not currently working as CPNs - an adjusted response rate of 54%. Completed consent forms accompanied all returned questionnaires. There was no significant difference in the adjusted response rate from Thorn graduates (53%) and CPNs (54%). A response rate of 54% may represent a significant non-response bias. However, given that 30 respondents were not currently, or had never worked as CPNs it is likely that the same was true for a proportion of the non-responders which may reduce the bias.

2.3.2 Demographics

Of the 114 respondents 51% were female, 90% classified themselves as white, and had a mean age of 40 years (range 24 – 57, s.d. 7.5). There was no significant difference in the demographic profile of the two groups. The majority of CPNs (69%) and Thorn graduates (64%) were employed at grade 'G'. Both CPNs and Thorn graduates had, on average, 15 years post registration experience and there was no significant difference in time spent

working in the community (CPNs 8 years; Thorn graduates 7 years). All Thorn graduates and 69% of CPNs were qualified to at least an undergraduate diploma level.

2.3.3 The role of the CPN

Although Thorn graduates had significantly smaller caseloads than CPNs (24 vs. 37; $t=4.53$, d.f.=110, $p<.001$), there was no significant difference in the proportion of patients with serious and enduring mental disorders, such as schizophrenia. All respondents indicated that they gave information and advice to both patients and carers about their illness and medication.

Respondents were asked to indicate whether a range of commonly used therapeutic techniques and skills were an important part of their role as a CPN. The list included the following medication management interventions: assessing patients' mental state, monitoring antipsychotic side effects and enhancing compliance. The results are presented in table 2.1. No significant difference between the two groups was observed both groups indicating that medication management interventions were an important part of their role. Significantly more Thorn graduates did report that the use of cognitive behavioural and family work interventions were an important part of their role.

Table 2.1. The role of the CPN

Intervention	Percentage of respondents who agreed that intervention was an important part of their role	
	CPN	Thorn graduate
Assessing mental state	96.9	100
Risk assessment	90.6	95.8
Monitoring side effects	87.3	95.8
Suicide prevention	87.3	91.7
Crisis intervention	71.9	85.7
Case management	65.6	77.6
Enhancing compliance	61.9	75.5
Mental health promotion	58.7	58
Giving depots	50	60.4
Anxiety management	40.6	44.7
Cognitive behaviour therapy[1]	31.3	65.3
Counselling	30.6	25
Family work[2]	27	61.2
Relaxation therapy	18	20.8

[1] $\chi^2 = 13.98$, df=2, p=.001. [2] $\chi^2 = 15.46$, df=2, p<.001

2.3.4 Assessing side effects

There was no significant difference in the frequency with which Thorn graduates and CPNs reported asking patients about antipsychotic side effects, with 80% of both groups assessing side effects at least once a month. The majority of both groups reported that they routinely asked patients about extrapyramidal symptoms (73% of Thorn graduates

vs. 65% of CPNs). Both groups reported that they were less likely to ask patients about anticholinergic effects, although Thorn graduates were significantly more likely to assess them than CPNs (56% vs. 30%; χ^2=7.34, d.f.=1, p=.007). Of the prolactin related side effects, sexual dysfunction was the most frequently assessed, but by a minority of both Thorn graduates (42%) and CPNs (24%). Amenorrhoea was assessed by 14% of Thorn graduates and 6% of CPNs. Less than 6% of CPNs in both groups reported that they routinely asked patients about other prolactin related side effects such as galactoria or gynocomastia. Just over half (52%) of the Thorn graduates but less than a third (31%) of CPNs indicated that they assessed weight gain, a difference that was statistically significant (χ^2=4.5, d.f.=1, p=.034).

2.3.5 Use of side effect assessment tools

Side effect assessment tools were routinely used by significantly more Thorn graduates than CPNs (62% v 25%; χ^2=8.61, d.f.=1, p=.003). The most widely used measure of antipsychotic side effects, in both groups, was the LUNSERS (Liverpool University Neuroleptic Side Effect Rating Scale; Day *et al.*, 1995). Significantly more Thorn graduates than CPNs reported using it in clinical practice (56% vs. 25%; χ^2=11.38, d.f.=1, p=.001). The Simpson Angus Extrapyramidal Side Effect Rating Scale (Simpson and Angus, 1970) was also used by a small, though significantly greater, number of Thorn graduates than CPNs (10% vs. 0%; χ^2 = 6.69, df.=1, p=.01). Fewer than 5% of both Thorn graduates and CPNs reported using the AIMS (Abnormal Involuntary Movement Scale; Guy, 1976). The use of self-developed measures to assess side effects

was also reported by significantly more Thorn graduates (24% vs. 5%, χ^2=9.16, d.f.=1, p=.002). No other measures were reported as being used.

2.3.6 Use of measures to assess psychopathology

The only recognised assessment of psychopathology reported to be used by respondents in either group was the K.G.V. (Krawiecka, Goldberg and Vaughn, 1977). Thorn graduates were significantly more likely to report using it in clinical practice than CPNs (40% vs. 5%, χ^2=21.73, d.f.=1, p<.001).

2.3.7 Use of measures to assess patients' beliefs about treatment and insight

None of the CPNs surveyed indicated that they routinely used any recognised measures of patients' beliefs about treatment or insight into their illness.

2.3.7.1 Factors that influenced practice

The effect of gender, ethnicity, experience, nursing grade, and level of educational attainment, on the use of the KGV and the LUNSERS were explored. There were no significant differences in any of these variables between Thorn graduates and CPNs who reported that they did or did not use either measure. CPNs who used the LUNSERS had significantly smaller caseload sizes (29 vs. 40; p=.022) and were slightly younger (36 years vs. 41 years; p=.031) than those who did not. This pattern was not found in Thorn graduates.

2.3.8 Knowledge about medication management

No significant difference in mean total scores on the knowledge questionnaire were observed between Thorn graduates (mean 14.64; range 8-18; s.d. 1.92) and CPNs (mean 13.58; range 9-17; s.d. 1.85). Scores were at the upper end of the 0-18 scale and suggest that CPNs in both groups had a reasonable understanding about psychopharmacology and the management of antipsychotic side effects.

2.3.9 Perceived need for training

Respondents were asked to rate their individual training needs on a 1 (low priority) to 9 (high priority) scale and results are shown in table 2.2. Generally a perceived need for training in all proposed areas was reported with the exception of anxiety management and relaxation. Both groups rated medication management interventions, risk assessment and suicide prevention as high priorities for training. However, Thorn graduates placed a significantly greater emphasis on the need for training in compliance and cognitive behavioural interventions. In contrast, CPNs placed significantly more emphasis on training in counselling.

Table 2.2. Perceived priorities for training

Training area	Priority for training score (1 low priority – 9 high priority)	
	CPN	Thorn
Suicide prevention	8.4	8.38
Risk assessment	8.35	8.47
Assessing mental state	8.28	8.44
Monitoring side effects	7.87	8.36
Crisis intervention	7.49	7.88
Care programme approach	7.37	7.42
Case management	7.29	7.77
Mental health promotion	7.23	7.55
Enhancing compliance[1]	6.77	7.58
Cognitive behaviour therapy[2]	6.57	7.78.
Family work[3]	6.48	8.02
Giving depots	6.24	6.61
Counselling[4]	6.07	5.14
Relaxation therapy	5.18	5.63
Anxiety management	5.6	6.06

[1] t=107, p=.010; [2] t= 108, p<.001; [3] t=109, p<.001; [4] t=2.3, p=.022

2.4 DISCUSSION

The aim of this study was to explore the impact of a recent training initiative on CPNs' medication management practice and knowledge. Both groups indicated that medication

management was part of their role. Thorn graduates reported using more standardised side effect and mental state measures than CPNs but were no more knowledgeable about psychopharmacology. The sample meets the requirements of the power calculation and the profile of respondents is generally comparable with the national survey of CPN services (Brooker and White, 1997). Although a greater proportion of respondents were educated to diploma level, the results may be cautiously generalised.

The majority of CPNs indicated that evaluating the effects of antipsychotic medication was part of their role. However, despite evidence from Wieden *et al.* (1987) that clinicians fail to detect a substantial proportion of side effects if they do not use assessment tools, only a minority of CPNs reported that they made use of such procedures in their practice. This suggests that respondents are failing to properly evaluate how well their patients are tolerating antipsychotic medication, a finding that is consistent with Bennett *et al.* (1995) and Gray (1998b). The small number of CPNs who reported using measures of psychopathology also appears to indicate that a regular review of the efficacy of medication is not being performed. The failure of CPNs to evaluate both the tolerability and efficacy of medication is incongruent with the standards set out in the National Service Framework (Department of Health, 1999) and may expose a lack of training in the use of such assessment tools. The high priority respondents, particularly Thorn graduates, placed on medication management training may indicate an awareness of the deficits in their current practice.

Respondents in both groups primarily used self-report scales such as the LUNSERS to detect side effects. Whilst self-report is useful it relies on patients being aware of side effects. This is not always the case, for example, patients may not always be aware of tremor, stiffness or abnormal body movements, and highlights the importance of other types of assessment tools which use observation and physical examination as a basis for rating.

Although the results from the knowledge component of the questionnaire should be treated with caution, no significant differences in knowledge about psychopharmacology were reported between the two groups. However, important deficits in knowledge among both groups, particularly about novel treatments, were observed. This may reflect the comparatively small amount of time within the Thorn programme that is devoted specifically to psychopharmacology. It is possible that a poor understanding about psychopharmacology may limit the strategies used by both groups to help patients manage antipsychotic side effects.

The results from this study suggest that training is, potentially, effective in enhancing certain aspects of CPNs' medication management practice. Although Thorn graduates reported using more standardised measures of psychopathology and side effects, only half stated that they were currently using such measures in their clinical practice. This finding is disappointing given that a considerable amount of time during the Thorn course is devoted to producing clinicians that are able to use the KGV reliably. The failure of Thorn graduates to routinely use the KGV suggests that they do not believe that it is

relevant to their clinical work or find it too time consuming to complete and score. It is also possible that external factors such as lack of clinical supervision following training may also have an important influence on practice. In this survey the effect of caseload size on practice was complex. CPNs who reported using the LUNSERS had a smaller caseload than those who did not. This may suggest that if the size of CPNs caseloads were reduced practice would improve. This may be true for simple self-report measures such as the LUNSERS. However, it seems unlikely that caseload size would increase the use of more complex measures to assess patients' psychopathology (such as the KGV) which require training to be able to use proficiently.

It is surprising that demographic factors such as grade and educational attainment did not explain variation in CPN and Thorn graduates practice. The finding that younger CPNs who have not attended Thorn training are more likely to use the LUNSERS would not be anticipated, and may suggest that younger, but not less experienced, staff are more motivated to seek out new skills. More research with a larger sample size is needed to explore factors that influence the practice of CPNs and Thorn graduates.

More Thorn graduates reported using the LUNSERS than the KGV in practice. This might suggest that measures that are quick and easy to complete are more likely to be incorporated into practice following training. The LUNSERS takes approximately 15 minutes and the KGV 90 minutes to complete. Alternatively, Thorn graduates may find the LUNSERS more relevant to the problems that their patients present with.

2.5 CONCLUSION

As discussed in chapter one, the evaluation of both the efficacy and tolerability of antipsychotic treatment is critical if side effects are to be minimised and compliance enhanced. The results of this study confirm previous research and suggest that CPNs do not use standardised measures to evaluate pharmacological interventions. Training does seem to be effective. Thorn graduates report using more assessment tools in routine clinical practice but they tend to prefer self-report checklists to identify side effects. As a model for enhancing CPNs' medication management skills, Thorn training has been partially successful, although more emphasis within the programme on psychopharmacology and the use of other side effect assessment tools may be warranted. However, the course is relatively time consuming and consequently it will not be possible to train all of the 6,700 CPNs currently in practice. An alternative model is needed to achieve widespread changes in practice rapidly and cost effectively. Delivering brief manualised training packages, which can be disseminated to entire community mental health teams, may be a more realistic approach to achieving this objective. A useful next step would be to develop a brief medication management training package based on the available evidence and test the impact of such an intervention on CPNs' knowledge and skills.

CHAPTER 3: DEVELOPMENT AND PILOTING OF THE MEDICATION MANAGEMENT TRAINING PROGRAMME

3.1 BACKGROUND

Antipsychotic medication is the mainstay of the treatment of schizophrenia. However, in chapter one it was demonstrated that compliance with antipsychotic medication is generally poor, and as a result relapse is common. The reasons for non-compliance are complex but there is good evidence that careful assessment, thoughtful prescribing and the use of psychological interventions that focus on working collaboratively with patients are effective in improving treatment concordance. CPNs are ideally placed to deliver such interventions in conjunction with the rest of the multi-disciplinary team. Training may be the most effective method of disseminating this knowledge and enhancing practice. Previous studies have shown that there is no apparent relationship between the duration of the training and clinical outcome. However, training that presents a clear treatment rational, gives trainees the opportunity to rehearse skills using role play and provides structured clinical supervision seems to be most effective.

Chapter two confirmed that without training practice is poor. CPNs make little use of valid and reliable assessment tools to assess patients' psychopathology or side effects, although their knowledge of psychopharmacology is reasonable. Thorn graduates, who had had some medication management training, were more likely to report using valid and reliable measures. However, there appears to be a preference among Thorn graduates for self-report tools that can be completed by patients and quickly scored. Because of the

relatively low proportion of Thorn graduates who report using measures such as the KGV, there is concern about the ability of training to enhance practice in the long-term.

Based on the evidence presented in chapters one and two there is a clear need for a medication management training course targeted at CPNs. As there is no apparent advantage, in terms of clinical outcomes, to intensive training courses such as Thorn, the medication management course should be relatively short. If the training is shown to be effective there is the added advantage of facilitating more rapid and cost effective dissemination of the intervention throughout the NHS.

Based on the evidence presented in chapters one and two the core components of the curriculum should be:

- Assessment of factors likely to affect compliance. This should include response to treatment, antipsychotic side effects, beliefs about medication and awareness of illness. This will allow the trainee to develop an individual patient formulation and target interventions more effectively. To maximise the impact of training it is pragmatic to use measures that are self report and/or quick to complete.
- Compliance therapy. There is good evidence from randomised controlled trials that compliance therapy techniques are effective in enhancing patients' beliefs about treatment and insight. Training in compliance therapy skills should form a substantive part of the programme.
- Behavioural tailoring. Although the quality of the evidence is weak such techniques may be useful and should form a small part of the training.

- Patient education. The evidence suggests that patient education is unlikely to enhance compliance. However, patients generally have a poor understanding of treatment and it would be unethical not to emphasise, within training, the importance of education in enabling informed decisions to be made.
- Psychopharmacology. In chapter two, CPNs' knowledge about psychopharmacology was found to be reasonable. However, in chapter one it was noted that there is a tendency to use higher than necessary doses of antipsychotic medication and that many side effects are undetected by clinicians. It is therefore important to ensure that training provides an overview of the safety and efficacy of antipsychotic and related pharmacological therapies (such as the use of anticholinergic medication to treat drug induced Parkinsonism). Training should also include information on the management of antipsychotic side effects to enable trainees to propose plans for treating them.
- Clinical supervision. In previous studies where training has been shown to be effective (Lancashire *et al.,* in review) structured supervision is cited as a critical method of changing trainees' clinical practice. Clinical supervision should therefore be an integral part of a training programme.

The curriculum outlined above is drawn from the evidence presented in chapters one and two. The methods used to train CPNs will be important in ensuring that they have acquired appropriate skills and knowledge. In chapter one, role-play rehearsal of new clinical skills prior to use in practice was a teaching method common to effective training interventions. Skills based medication management training may benefit from adopting such an approach to developing trainees' clinical skills.

A preliminary investigation would be useful in establishing whether a brief training package is effective in enhancing clinicians skills and knowledge to a level likely to produce clinically meaningful outcomes. If the training was shown to be effective, further exploration, within the context of a randomised controlled trial, would then be warranted.

3.2 THE MEDICATION MANAGEMENT INTERVENTION AND COURSE

A group of clinical and academic specialists met to review the literature and finalise the curriculum for the medication management intervention and training course. This group developed medication management training and treatment manuals to ensure consistency of training and enhance fidelity to the intervention (the final version of the training and treatment manuals can be found in appendices 2 and 3).

3.2.1 Treatment procedure

All patients were seen individually and the duration and frequency of sessions was defined by individual CPNs according to each patient's level of cognitive function. It was recommended that the intervention would initially involve approximately 20 hours of individual work followed by ongoing, monthly, top-up sessions. The aim of the medication management intervention was to help patients examine the use of pharmacological interventions to treat their illness and also to provide them with skills to help them manage their medication in the future.

The first stage of the intervention, which normally lasted several sessions, was the completion of formal clinical measures of psychopathology, insight, attitudes towards treatment and antipsychotic side effects. During this stage of the intervention CPNs helped patients to identify specific problems and targets for treatment as well as engaging the patient in discussing their medication. A clear treatment rationale, that the CPN wanted to work collaboratively with the patient in addressing issues around medication. was presented. A formulation and plan of therapeutic tasks and homework was then discussed with the patient. Considerable time was devoted to the careful assessment and review of the patient's medication as it was hoped that this would not only aid engagement but also have some therapeutic benefit.

3.2.2 Structure of sessions and general therapeutic skills

At the beginning of each session CPNs set an agenda with the patient with specific and relevant areas for discussion. Time limits were established and the CPN carefully planned and structured each session appropriately for each patient dependent on their level of functioning. General therapeutic approaches included: carefully eliciting and responding to verbal and non-verbal feedback; understanding the patient's views of medication and treatment; and encouraging the patient to take an active role during the sessions. Guided discovery was a central skill with the CPN helping the patient to explore problems and draw their own conclusions. These general skills and structure formed the foundations for the application of more specific medication management and compliance therapy techniques.

3.2.3 Medication management/compliance therapy techniques

3.2.3.1 Providing information

Providing patients with information about their illness and treatment was an important part of the intervention. Misconceptions and lack of understanding about any aspect of treatment were clarified at any opportunity.

3.2.3.2 The illness timeline

Patients identified when they, or significant others, first realised they had psychiatric problems and the course of their illness and the positive and negative effects of treatment over time were then plotted. Close attention was paid to helping the patient identify when their mental health had been particularly good and when it had been not so good. The purpose of this exercise was two-fold; firstly to help the patient make any links between stopping medication and worsening psychopathology, and secondly to identify and examine negative experiences of treatment, particularly where medication had been forcibly administered.

3.2.3.3 Normalising rationales

Drawing an illness timeline was linked to the use of normalising rationales to explain both psychotic pathology and the need for maintenance treatment. A rationale was discussed with the patient and the typical symptoms of, and possible genetic predisposition to, schizophrenia were described. The vulnerability-stress model (Zubin, 1987) was then explained in detail, with the CPN making specific links to the work done

in reviewing the illness timeline, to help the patient identify that their psychotic symptoms may be caused by an increased susceptibility to stress. If the patient accepted this rationale then further work could be undertaken with the CPN helping the patient to draw analogies to other physical illnesses, such as diabetes or asthma, where maintenance treatment is necessary to prevent relapse.

3.2.3.4 Drawing up a balance sheet

Patients were helped to draw up a balance sheet to highlight both the positive and negative aspects of treatment. Emphasis was placed on identifying the less obvious effects of medication. Dependent on the patient's level of functioning this activity could be done as homework with the CPN expanding and clarifying the work that the patient had already undertaken.

3.2.3.5 Testing beliefs about illness and medication

Patients' beliefs about their illness and medication were tested by adapting the cognitive behavioural procedures for examining delusions (Chadwick *et al.*, 1996). Beliefs about illness and medication were challenged: the plausibility of the beliefs was questioned; the beliefs were reformulated as being an understandable response to, and way of making sense of, specific experiences; and a personally meaningful alternative was constructed. Finally, the patient's original belief and the alternative were assessed in light of the available information.

3.2.3.6 Specific problems with medication

Specific problems with medication, such as side effects, were examined using a problem solving strategy (Hawton and Kirk, 1989). A problem was selected and a target was agreed. The broad steps necessary to achieve this goal were identified and the patient decided, in detail, the practical and realistic tasks that would be necessary to achieve this goal. Progress was reviewed in subsequent sessions.

3.2.3.7 Examining the consequences of stopping medication

Patients were asked to project the positive and negative aspects of stopping medication. Again this was a potential homework task dependent on the patient's level of functioning.

3.2.3.8 Long term plans

Patients were asked to look six to twelve months into the future and identify a goal they wanted to achieve. A problem solving strategy was utilised to identify tasks needed to achieve this objective.

3.3 Medication management training course

The course was designed for rapid dissemination and teaching activities were carefully structured and planned to mirror the treatment manual. It was delivered as a day release, nine week, 72 hour programme consisting of four major components, with the aim of providing mental health nurses with practical skills in working with patients collaboratively on medication issues. Eight weeks after the end of the course a follow-up

day was held to review the application of skills to clinical practice (a total of 80 hours contact time). The four key components of the training were assessment, cognitive and medication management skills, psychopharmacology, and clinical supervision. A multi-disciplinary team, including a combination of academic and clinical staff, provided teaching.

In the first component of the course, trainees were taught to use a battery of valid and reliable assessment tools to evaluate treatment with antipsychotic medication and derive a formulation of the patient's problems or concerns about their medication. The formulation was used to guide the selection of targeted medication management interventions. In order to evaluate the efficacy of antipsychotic treatment regimes trainees learned to assess patients' psychopathology using the Positive and Negative Syndrome Scale (PANSS; Kay *et al.,* 1989a), a comprehensive and widely used measure, the completion of which is based on the clinician undertaking a Structured Clinical Interview (SCI). The PANSS was selected because it is extensively used in the UK, training materials are available, and it is relatively quick to complete.

Trainees also learned to use a range of specific self-report measures. Self-report measures were used because, as discussed in chapter two, clinicians appear to prefer them and are more likely to continue to use them following training. Two measures were selected to assess patients' beliefs about treatment. The Hogan Drug Attitude Inventory (DAI-30; Hogan *et al.,* 1983) and the Insight Scale for Psychosis (IP; Birchwood *et al.,* 1994). The DAI-30 is a 30-item scale used to determine patients' beliefs about antipsychotic

medication and takes approximately 30 minutes to complete and score. The IP is an eight-item scale exploring the three components of insight (awareness of illness, ability to relable symptoms and acceptance of the need for treatment). These measures were selected because they are widely used, have good validity and reliability and are quick to complete and score.

Selecting a measure to detect antipsychotic side effects was more complex. The advantages of self-report measures have already been stated. However, as discussed in chapter two, a reliance on the use of self-report may mean that some side effects go undetected. However, introducing clinicians to multiple measures to detect side effects may make the assessment overly complex and time consuming, reducing the likelihood that it would be completed and appropriate targets for treatment selected. Therefore, the main side effect measure which trainees learned to use was the Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS; Day *et al.,* 1995) a fifty-one item scale to screen for unwanted side effects based on the UKU side effect measure (Lingjaerde *et al.*, 1987). Each item is rated on a five-point scale and scoring involves grouping items into side effect clusters (EPS, prolactin, anticholinergic, allergic, etc.). The measure takes approximately 15 minutes to complete and 10-20 minutes to score, has been shown to be valid and reliable and, as demonstrated in chapter two, is widely used.

Trainees practised using these measures through role-play and ratings of videotaped patient interviews. Within the role-plays the measures were used to identify specific problems and areas of concern that the trainees role-play partner wanted to address.

The second component of the course focused on developing trainees' skills in using psychological interventions (compliance therapy, behavioural tailoring, patient education) to enhance compliance. Trainees were given an overview in compliance research and the medication management treatment rationale. To facilitate teaching, discrete clinical interventions were described (reviewing illness history, testing beliefs about treatment, exploring ambivalence, and giving information). Video role-play was used to allow trainees to rehearse each discrete intervention and receive feedback from the rest of the group about what they did well within the role-play and what they could have done differently (Gask, 1999).

The psychopharmacology component of the course provided a comprehensive overview of the mode of action and use of antipsychotics to supplement trainees more specific medication management work. The Bethlem and Maudsley NHS Trust Prescribing Guidelines (Taylor *et al.*, 1999) were used as a basis for teaching and to provide trainees with evidential clinical practice guidelines. Teaching, using the guidelines as a template, focused on effective treatment strategies, the management of antipsychotic side effects, and the treatment of refractory illnesses.

Regular, weekly, clinical supervision formed a critical component of the course integrating skills learnt in the classroom into clinical practice. Each trainee presented a patient they were working with, concluding the presentation by suggesting a supervision question for discussion within the group. Following the discussion, an action plan was

agreed. On the follow-up day trainees presented an update on their progress, having implemented the action plan.

3.4 AIMS OF THE PILOT INTESTIGATION

The aim of this study was to establish whether the model of medication management training described above has sufficient impact on CPNs' clinical skills and knowledge to warrant further investigation. This was established by testing the hypotheses that medication management training would:

- Enhance trainees' compliance therapy skills as measured using the Cognitive Therapy Scale (Vallis *et al.*, 1986; appendix 4 and 5).
- Increase trainees' knowledge about medication management as measured using the Knowledge about Medication Management Questionnaire (appendix 6).
- Demonstrate that trainees can reliably evaluate pharmacological interventions by rating patients' mental state using the Positive and Negative Syndrome Scale (PANSS; Kay *et al.*, 1989a).

Because the other measures (DAI-30; IP; LUNSERS) taught during the course were self-report, it is not necessary (or possible) to establish trainees' reliability in using them.

Feedback from trainees on the relevance of training to their clinical practice, their ability to apply what they had learned in practice and their overall satisfaction with training was rated on a satisfaction with training questionnaire.

3.5 METHOD

3.5.1 Design

The study has a within-subjects repeated measures design. Trainees were recruited from three mental health Trusts in south London and were accepted on to the course if they were registered mental health nurses currently working predominantly in the community with patients with serious and enduring mental disorders.

3.5.2 Primary outcome measure

3.5.2.1 Cognitive Therapy Scale (CTS; Vallis et al., 1986; appendix 4)

A ten-minute standardised role-play task (appendix 5) derived from the method described by Scott et al. (1999), focusing on a patient's specific problem with antipsychotic medication, was performed pre- and post-training. An experienced third party 'actor' role-played the patient. These were videotaped and blind rated by a trained cognitive therapist using the cognitive therapy scale at the end of training. The CTS is extensively used in both North America and the United Kingdom and is a valid and reliable 10-item measure of clinicians' general and specific clinical skills. Each of the items - agenda setting, feedback, understanding, interpersonal effectiveness, collaboration, pacing and efficient use of time, guided discovery, strategy for change, application of specific medication management techniques and an overall clinician rating - were rated on a seven-point scale ranging from poor (0) to excellent (6) producing a total score of between 0 and 60. A satisfactory score for each item is defined as 3, and for the total as 30. Each item has four anchor points to facilitate rating.

3.5.3 Secondary outcomes measures

3.5.3.1 The Knowledge about Medication Management Questionnaire (Appendix 6)

The 16-item multiple-choice Knowledge about Medication Management Questionnaire was administered pre- and post-training. The questionnaire was specifically developed for the study as no appropriate measure could be identified within the literature that reflected the medication management course curricula and recent developments in psychopharmacology, including the introduction of new drugs. Trainees were presented with 16 questions that related to case vignettes with five possible responses, of which only one was correct. The questionnaire produces a total score ranging from 0 to 16. The questionnaire was designed to have content validity by including questions on key aspects of the medication management intervention taught within the course. To test this a Consultant Psychiatrist and a Clinical Pharmacist completed the questionnaire and were able to get 100% of the questions correct. Test re-test reliability was established by correlating scores on the Knowledge about Medication Management Questionnaire in a group of 10 mental health nurses not associated with the project. Questionnaires were completed twice with a ten-week interval between assessments to mirror training, and good test re-test reliability was demonstrated.

It is possible that testing trainee knowledge may in itself influence the outcome of training by enhancing trainees' motivation to study for the test. To minimise this effect trainees were not given advance notice of the test and were not allowed to keep copies of the assessment.

3.5.3.2 Positive and Negative Syndrome Scale (PANSS; Kay et al., 1989a)

Reliability in assessing patients' mental state using the PANSS was established using the method described by Peuskens *et al.* (1995). Trainees' ratings of a video of a patient being interviewed using the structured clinical interview (SCI; Kay *et al.*, 1989b) were compared to a gold standard. A rating to within ±1 point of the gold standard for 80% of the items demonstrated satisfactory inter-rater reliability (Peuskens *et al.*, 1995).

3.5.3.3 Satisfaction, relevance and application of training (appendix 7)

At the end of the course trainees completed a questionnaire asking them to rate how satisfied they had been with the content of the course and the quality of the teaching. They also rated how relevant the course was to their clinical practice. Each rating was made on a four-point Likert type scale. Trainees also indicated if they were able to incorporate the skills that they had learnt into their routine clinical practice.

3.5.4 Statistical analysis

To identify within group differences post-training the Wilcoxon test for related samples was used. Two-tailed tests were used as the most conservative method of analysis even when the comparisons were supported by a specific hypothesis. Standard parametric statistics also produced the same result. The McNemar test was used to test for changes in the proportion of trainees who achieved a satisfactory standard on the CTS item and total scores.

3.6 RESULTS

3.6.1 Demographic characteristics of the trainees

Although fifteen trainees completed the two courses, eight in cohort one and seven in cohort two, three trainees did not complete the measures because they were absent when they were administered. Data are therefore reported on the twelve trainees who completed all the assessments. There were no significant differences in the demographic profile of trainees who did or did not complete all the assessments.

The mean age of the 12 trainees who completed the course was 32 years (range 26-41), 50% were male and the majority (58%) classified themselves as being of white ethnic origin. All trainees were mental health nurses working in the community with a mean length of experience of six years. The majority of trainees (75%) held diploma level qualifications or higher. There were no significant differences between the two cohorts. Trainees who completed the course had an average attendance of 88% of the taught components. The demographic profile of trainees is generally similar to that reported in other training studies (Lancashire *et al.*, under review; Brooker *et al.*, 1994) and the most recent survey of Community Mental Health Nurses in England and Wales (Brooker and White, 1997). Trainees in this study have, however, received more post-registration training and are from a more diverse ethnic background than the national average (Brooker and White, 1997).

3.6.2 The Cognitive Therapy Scale

Table 3.1 shows mean CTS total and item scores pre- and post-training. At post-training the CTS total score had doubled and, with the exception of guided discovery, significant improvements in each of the items were also observed. A mean improvement from barely adequate to satisfactory was observed for the application of medication management techniques.

Table 3.1. CTS total and item scores pre- and post-training

	Pre-training		Post-training		
CTS item	**Mean**	**s.d.**	**Mean**	**s.d.**	**P**
Agenda setting	.77	.83	2.08	.86	=.003
Feedback	1.31	1.18	2.92	1.12	<.001
Understanding	1.54	.97	3.23*	1.24	<.001
Interpersonal effectiveness	2.15	.69	3.38*	1.12	=.001
Collaboration	1.77	.73	3.00*	.82	=.001
Pacing and efficient using of time	1.31	1.11	2.69	.85	=.002
Guided discovery	1.85	1.07	2.77	.93	Ns
Strategy for change	.85	.80	3.00*	.82	<.001
Application of medication management techniques	.92	.86	3.00*	1.15	<.001
Clinician rating	1.62	.96	2.85	1.07	=.003
Total score	**16**	**8.75**	**30.6****	**9.07**	**<.001**

*Satisfactory standard defined as ≥3 **satisfactory total score defined as ≥30

ns=not significant

One of the trainees had satisfactory CTS scores pre-training, five (42%) achieved a satisfactory total score of ≥30 post-training. However, this difference was not statistically significant. Table 3.2 shows the proportion of trainees achieving a satisfactory standard on each item of the CTS.

Table 3.2. Proportion of CPNs who were rated as satisfactory on the CTS pre- and post-training

	Pre-training		Post-training		
CTS item	**n**	**%**	**n**	**%**	**P**
Agenda setting	2	17%	2	17%	Ns
Feedback	2	17%	7	58%	[.063]
Understanding	2	17%	8	67%	.031
Interpersonal effectiveness	4	33%	9	75%	[.063]
Collaboration	1	8%	8	67%	.016
Pacing and efficient using of time	2	17%	7	58%	[.063]
Guided discovery	4	33%	7	58%	Ns
Strategy for change	0	0%	8	67%	.008
Application of medication management techniques	0	0%	6	50%	.031
Clinician rating	2	17%	8	67%	.031
Total score	**1**	**8%**	**5**	**42%**	Ns

ns=not significant, [] trend

3.6.3 Knowledge about Medication Management

Pre-training, the mean score on the Knowledge about Medication Management Questionnaire was 7.9 with trainees getting just under half of the questions correct. Post-training the mean score increased to 10.5 with trainees getting two thirds of the questions correct. This equates to a mean improvement of 33% which is highly statistically significant ($p<.001$).

3.6.4 Mental state assessment

Eight (67%) trainees rated the video of a patient being interviewed to a satisfactory standard. The mean number of errors (items not rated to within ±1 point of the gold standard) per trainee was 4.8 (16%). No significant difference in trainees' concordance with the gold standard was observed between positive symptoms (mean 1.1 errors), negative symptoms (mean 1.8 errors) and general psychopathology (mean 2.0 errors).

3.6.5 Satisfaction, relevance and application of training

All trainees reported that they were either satisfied or very satisfied with the content of the course and the quality of the teaching. All trainees also reported that they were able to incorporate the assessment tools and skills into their day to day clinical practice. Trainees did feedback that they would like less time spent on role-play and more on psychopharmacology.

3.6.6 Prediction of change

Linear regression was used to identify any predictors of improvements in clinical skills and knowledge. CTS and Knowledge about Medication Management Questionnaire change scores were used as the dependent variables and age, gender, ethnicity, attendance, length of experience, clinical grade and highest level of previous academic attainment were used as the independent variables. No predictors were found although there was an association between attendance and change in CTS total score ($r=.586$, $p=.045$).

3.7 DISCUSSION

The results generally supported the hypothesis that brief training enhances trainees' medication management skills and knowledge. The results also demonstrated that the majority of trainees could reliably assess a patient's mental state using valid and reliable assessments. A high degree of satisfaction with the training was reported.

The Cognitive Therapy Scale total and item scores were rated as being barely adequate-to-mediocre pre-training. Knowledge about Medication Management Questionnaire scores also suggested a poor pre-training understanding about medication management. These findings demonstrate that trainees were not skilled in structuring sessions or working collaboratively with patients using basic cognitive therapy skills. The application of specific medication management techniques was also rated as being 'barely adequate'. The findings suggest that prior to receiving training, trainees were not sufficiently skilled to apply techniques which have been shown to be effective in

enhancing compliance (Kemp *et al.*, 1997). The poor pre-training scores on the Knowledge about Medication Management Questionnaire demonstrate that trainees had a poor understanding of assessment measures, strategies for enhancing compliance and antipsychotic side effects. This finding is consistent with the poor rates of detection of antipsychotic side effects by mental health nurses reported by Bennett *et al.* (1995) and the findings reported in chapter two.

All trainees showed an improvement in CTS scores following training. Almost half of the CPNs who received training were able to demonstrate satisfactory medication management skills at the post training assessment compared to none pre-training. These trainees may have acquired sufficient skill and knowledge to apply the training with sufficient fidelity to improve patient outcome. This hypothesis will, of course, need to be tested within the context of a randomised controlled trial. These improvements are consistent with the satisfactory levels of clinical skills observed by Brooker and Butterworth (1993) and may suggest that, as discussed in chapter one, brief targeted programmes are as effective as more extensive courses in facilitating the implementation of psychosocial interventions.

However, only just over half of the trainees achieved a satisfactory level of skill and refinements to the programme will be needed to maximise the potential impact of training on patient clinical outcomes. Improvements in some CTS items were found whilst others did not change significantly. For example, post training 75% of trainees demonstrated a satisfactory level of interpersonal effectiveness but only 17% in agenda setting. This

suggests that, in future, more time is spent on developing these skills. However, increasing the amount of time spent rehearsing clinical skills is contradictory to the feedback from trainees who wanted to spend less time in role-play.

The weak correlation between skills acquisition and attendance suggests that trying to improve attendance may be useful in improving CTS post-training. Attendance in this study was high although some level of absenteeism was unavoidable. However, careful planning with service providers (e.g. running the course on days when there are no ward rounds) and the involvement of trainees' line managers in facilitating and encouraging participation may help improve attendance.

Training was effective in improving knowledge about medication management and was consistent with Lancashire *et al.* (under review) who also found that training improved trainees' knowledge. Skills in assessing patients' mental state were also demonstrated to be satisfactory for the majority of trainees. These results suggest that trainees understand the treatment rationale, are able to perform relevant assessments, derive a formulation and target appropriate medication management interventions to address patients' specific problems with their medication.

The high degree of satisfaction with the training and strong indication that trainees found it to be both applicable and relevant to their clinical practice is consistent with the findings reported in chapter two. Suggesting that the medication management

intervention provides clinicians with the skills that they need but are not provided with within current training initiatives.

The cost of providing medication management training was £1,474 per trainee, including replacement costs (a detailed breakdown of costs can be found in appendix 9). Given that the training is manualised and can potentially be facilitated by an appropriately trained clinician there is a potential for rapid dissemination.

The improvements in clinician skills and knowledge and the reported satisfaction with, and relevance to practice of, the medication management training suggest that an investigation into the impact on clinical outcome may be warranted.

3.8 CONCLUSION

Brief targeted training that facilitates the rapid dissemination of psychosocial interventions into routine clinical practice is needed to meet the requirements of the National Service Framework (Department of Health, 1999). The results of this study suggest that the medication management training programme leads to enhanced clinical skills and knowledge. However, whilst skills are enhanced only half of the trainees were able to demonstrate satisfactory levels. This suggests that the model of training may need to be revised to ensure that a higher proportion of trainees achieve a satisfactory standard. However, the improvements are sufficient to warrant a further large-scale investigation into the impact of training on clinical skills and patient outcomes.

CHAPTER 4: RANDOMISED CONTROLLED TRIAL

The first three chapters have established that non-compliance with antipsychotic medication is a major preventable cause of psychiatric relapse. Psychological and pharmacological interventions, such as compliance therapy and effective detection and management of antipsychotic side effects (medication management), are effective in enhancing treatment concordance. Training is potentially an effective method of disseminating medication management interventions so that CPNs can deliver them in routine clinical practice. A survey of CPNs confirmed that current medication management practice is poor and that although training is enhanced in those who have received training in psychosocial interventions, such models do not lend themselves to the large-scale dissemination of medication management interventions throughout the NHS. Based on the available evidence a pilot medication management training package was developed and piloted. Significant improvements in CPNs' knowledge and skills were found post training. It is reasonable therefore to progress from this pilot work to address the central research question:

- Does medication management training result in improved clinical outcomes for patients?

4.1 METHODS

The most robust method for answering this question is a randomised controlled trial comparing the clinical outcomes of patients treated by CPNs who have received medication management training with those delivering routine care. No previous studies

have used such a methodology to evaluate the impact of a training intervention. This trial will also therefore develop and test methodologies for undertaking such an investigation.

4.2 MAIN HYPOTHESES

The main hypotheses of this trial were to establish that compared to standard care, the application of a medication management intervention for patients with schizophrenia delivered by CPNs in routine clinical practice would produce significant improvements in patients':

1. Psychopathology, because of increased treatment compliance
2. Functioning, because of increased treatment compliance
3. Attitudes towards treatment
4. Compliance with antipsychotic medication
5. Insight into their illness
6. Antipsychotic side effects, because of more appropriate prescribing
7. Service utilisation, because of increased treatment compliance
8. Prescribed antipsychotic medication

4.2.1 Other issues investigated

The trial also aimed to establish that revised brief training was effective in providing CPNs with the knowledge and skills necessary to effectively deliver the medication management intervention. Three questions were asked:

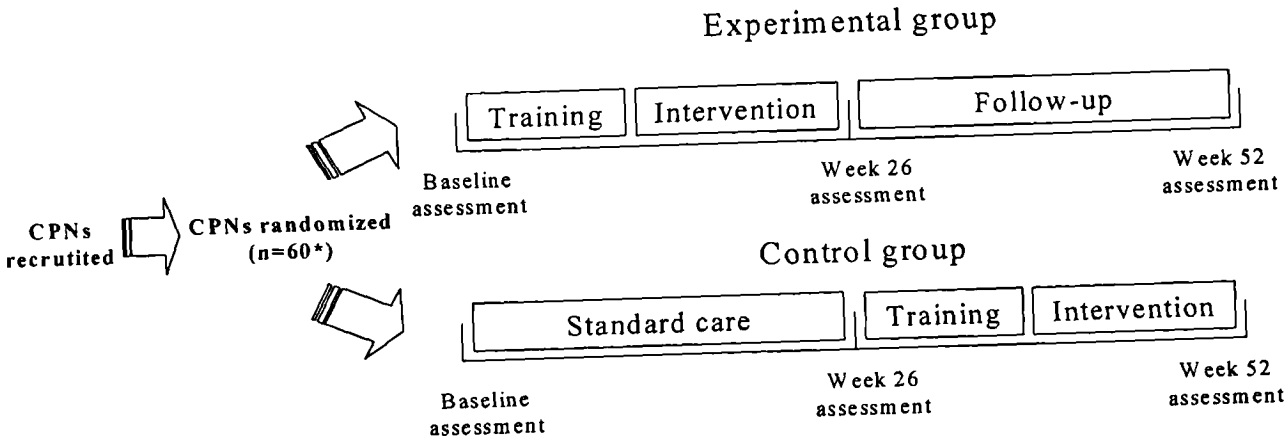
1. Would CPNs' clinical skills be enhanced?
2. Could they reliably assess patients' psychopathology?

3. Would knowledge about psychopharmacology be increased?

4.3 DESIGN

Sixty CPNs were recruited to the trial from two NHS Trusts. They were organised into 12 clusters based on the geographical location of the community mental health team or GP surgery where the CPN was based. They were then randomised into either the experimental or waiting list control groups. CPNs in the experimental condition received 80 hours of training to deliver a medication management intervention. Those in the waiting period continued with their standard practice for 26 weeks and then received the same training. Each CPN identified two patients on their caseload to participate in the trial. These patients completed a battery of self-report and researcher rated outcome measures at baseline and again after 26 and 52 weeks (Figure 4.1). Because patients are not independent of each other (i.e. pairs share the same CPN), the most conservative method of analysing the data is to take the mean of the scores from the CPNs' two patients. CPNs' clinical skills and knowledge were assessed pre- and post-training.

Figure 4.1 Trial Design



*Each identified two patients on their caseload. Mean score for both patients used for analysis

4.4 ALTERNATIVE DESIGNS

The design was chosen to compare clinical outcomes in patients treated by CPNs who had been trained to deliver a medication management intervention with those of CPNs delivering routine care during the control period. CPNs in the control group then received training after the week 26 assessments had been completed, at which point they served as their own controls. Comparison with a control group, where clinical outcome was being monitored, was important because, as observed in chapter one, compliance tends to improve under scrutiny. It was also important to assess patients after a follow up period, rather than pre- and post-training only, because if improvements are not sustained the durability of the intervention may be in question (Hickie *et al.*, 1995).

Alternative designs such as control groups made up of non-active or placebo training were considered but rejected. Placebo training was rejected for two main reasons: firstly, it would be unethical and expensive to train CPNs to deliver an intervention which was known to be ineffective, secondly, it would have been difficult to get the support of the CPNs in identifying suitable patients for the study. Standard care, as a control, was rejected because of anticipated difficulties in recruiting CPNs to participate and facilitate access to patients in a study for which they received no benefit.

4.5 POWER CALCULATION

The required sample size of 60 CPNs for this trial was based on the following assumptions:

1. The primary outcome of interest is improvement in patients' psychopathology.
2. The primary outcome measure is the total score for the Positive and Negative Syndrome Scale (PANSS Kay *et al.*, 1989a).
3. The mean common standard deviation for the PANSS is 12.4. This is derived from data from drug trials (Marder *et al.*, 1997; Beasley *et al.*, 1997; Peuskin *et al.*, 1995) previous compliance interventions (Macpherson *et al.*, 1996a) and psychometric testing of the PANSS (Kay 1990; Bell *et al.*, 1992; Peralta and Cuesta 1994).
4. The CPN is the unit of analysis.
5. No previous trials of compliance interventions have demonstrated a significant effect of treatment on patients' psychopathology. A ten-point difference in the PANSS total scores between the experiemental and control groups was considered to be clinically important and feasible to achieve. This was based on evidence from the compliance therapy trial (Kemp *et al.*, 1996; 1998) and previous studies that have evaluated the impact of CPN training on patients' psychopathology (e.g. Brooker *et al.*, 1994).
6. The most conservative method of analysis would be a comparison of the differences in mean scores between the two groups at the week 26 assessment (controlling for baseline scores) using an analysis of co-variance (ANCOVA).
7. The level of significance for detecting a training effect of 10 points on the PANSS was set at 5%. The degree of certainty that a true difference between groups (if at least 10 points) would be detected was 80%.
8. The patient drop out rate in a previous training trial was 20% (Lancashire *et al.*, under review). A similar drop out rate was assumed in this trial.

The power analysis was performed using NQuery advisor.

4.6 INCLUSION AND EXCLUSION CRITERIA

4.6.1 CPN inclusion criteria

CPNs were recruited to the trial if they met the following inclusion criteria:

- Registered nurse on either part 3 or 13 of the UKCC (United Kingdom Central Council) register.
- Have at least 12 months post registration experience.
- Working in a community setting with a caseload of predominantly psychotic patients.

4.6.2 Patient inclusion and exclusion criteria

Each CPN who agreed to participate in the study identified two patients on their caseload who they would be working with for the duration of the trial. These patients were then visited by a researcher and screened to ensure that they met the trial inclusion/exclusion criteria:

4.6.2.1 Inclusion criteria.

- Currently on the caseload of a randomised CPN.
- Gave written informed consent to participate in the trial.
- Had a recorded ICD-10 diagnosis of a psychotic disorder (WHO, 1992).
- Currently, or a prescribing doctor recommended, taking antipsychotic medication.
- Known or suspected poor treatment adherence (reported by the CPN) or within the previous twelve months at least one admission or relapse.

4.6.2.2 Exclusion criteria

- Patients suffering from moderate or severe learning disabilities concurrent with schizophrenia.
- Patients being treated by forensic psychiatric services.
- Inpatients who have remained in hospital for more than six months prior to the start of the training period.
- Patients suffering from organic brain disorders.

4.7 METHOD OF RANDOMISATION

CPNs were allocated to experimental or control groups using a restricted cluster randomisation procedure to: 1. ensure equal numbers of trainees in each group; and 2. to minimise the risk of contamination (caused by CPNs who work in the same office sharing information about the training). Randomisation sequences were prepared from a table of random numbers, in random permuted blocks (appendix 8). As randomisation was with small numbers of clusters, blocks of four were used.

The prepared randomisation lists were then transferred to a set of sealed envelopes, numbered from one to twelve, containing a card indicating which group the cluster had been allocated to. Once twenty CPNs were recruited to the trial they were organised into four clusters (numbered one to four) with five trainees in each (keeping those who worked in the same building together). The randomisation envelope corresponding to their cluster number was then opened and the CPNs were informed of the date when

training would occur. The CPNs name, cluster number and training allocation were entered into the trial logbook immediately after randomisation and prior to the commencement of training. This process was repeated on two more occasions (cluster numbers five-eight and nine-twelve). The researchers undertaking patient assessments did not have access to the randomisation envelopes or log.

4.8 RECRUITMENT OF CPNs

Two mental health NHS Trusts were approached and agreed to participate in this trial. A trial co-ordinator, a senior nurse within each NHS Trust, recruited CPNs, who met the inclusion criteria, to participate in the trial. CPNs were recruited by advertising the course within the Trust in three ways: writing directly to CPNs; putting posters on notice boards; and placing advertisements in the local recruitment bulletin. CPNs who agreed to attend the training were informed by the trial co-ordinator that they would be randomly allocated to attend a training course starting on two different dates 26 weeks apart. It was also explained that they would need to identify two patients on their caseload who they would continue to work with during the trial and who met the inclusion/exclusion criteria. They also had to facilitate patient assessments conducted at baseline, week 26 and week 52.

4.9 RECRUITMENT OF PATIENTS

4.9.1 Obtaining informed consent

At the screening visit, patients were given a brief description of the trial and the interventions that their CPN would be using. It was explained that the aim of the study was to improve the care they received by providing additional training to the CPN who was treating them. They were informed that the assessment procedure would include questions about their mental health and their experiences of taking antipsychotic medication. Patients were encouraged to ask as many questions as they wished which were answered as comprehensively as possible by the research worker. Patients were also given an information sheet (appendix 10). They were not asked to make an immediate decision but if they were happy to take part the researcher would make another appointment to visit them and complete the interview. At this second visit patients were asked to sign a consent form (appendix 11).

4.10 PROCEDURES TO ADMINISTER OUTCOME MEASURES AND PROTECT AGAINST SOURCES OF BIAS

All patient interviews were conducted by one of two trained research workers who were blind to the training condition. Both researchers were psychology graduates and were experienced at interviewing patients with psychotic disorders. They also received additional training in using all of the patient assessments, including the PANSS. Training included role playing the interview, performing the interview with patients under supervision, and practice interviews with patients. Reliability in rating the PANSS was achieved using the method described by Peuskens *et al.* (1995) and outlined in chapter 3.

A high degree of inter-rater reliability was achieved for both research workers (researcher one, two errors 93% correct; researcher two, four errors, 87% correct).

The researcher was given the contact name, address and phone number of a CPN, by the lead investigator, and asked to arrange to visit the two patients they had identified to participate in the study. Both the research worker and CPN were instructed not to discuss any aspect of the trial or training. After each visit the patient's case record was placed in a locked filing cabinet to which the research worker did not have access. A third party who was not involved in data collection entered the data from the patient's case record onto a computerised database, which was password protected.

4.11 TIMETABLE FOR TRIAL

The timings of the medication management training, intervention and patient interviews are shown in table 4.1. The courses were staggered to allow a reasonable amount of time for patient interviews to be completed. The dates for the courses were agreed with the trial co-ordinator well in advance of the start of the course and a meeting was held with all CPNs participating in the study outlining what would be required of them.

Problems were anticipated in ensuring that all the assessments were completed on time. A four-week window was therefore agreed for each of the three assessments phases. If the assessment was not completed within this time then it was counted as missing data but the patient continued in the trial.

Figure 4.1, Timetable of trial

Group	j	f	m	a	m	j	j	a	s	o	n	d	j	f	m	a	m	j	j	a	s	o	n	d	j
One			•	Training					•					•											
Two	•						•	Training					•												
Three					•	Training					•						•								
Four				•						•	Training					•									
Five											•	Training					•						•		
Six													•						•	Training					•

• = Patient assessment window

4.12 OUTCOME MEASURES

At baseline all patients were assessed using the following outcome measures which were then repeated at week 26 and 52 (table 4.2). Care was taken when selecting measures that the total time taken to conduct each patient visit should be no more than 90 minutes.

Table 4.2 Assessment procedure

Measure	Method of data collection	Baseline	Week 26	Week 52
Positive and Negative Syndrome Scale (PANSS)	Patient interview	●	●	●
Global Assessment of Functioning (GAF)	Researcher rating	●	●	●
Hogan drug attitude inventory (DAI-30)	Patient self-report	●	●	●
Composite measure of compliance	CPN rating	●	●	●
Insight Scale for Psychosis (IS)	Patient self-report	●	●	●
Liverpool University Side Effect Rating Scale (LUNSERS)	Patient self-report	●	●	●
Demographic information	Case note review	●		
Prescribing information	Case note review	●	●	●
Service utilisation	Case note review	●	●	●

● = assessment

4.13 PRIMARY OUTCOME MEASURES

4.13.1 Positive and Negative Syndrome Scale (PANSS; Kay *et al.*, 1989a)

The Positive and Negative Syndrome Scale (PANSS) was chosen as a well researched psychometric instrument for evaluating the symptoms of schizophrenia. Thirty-items are rated on a seven point scale which follows the general format of the Brief Psychiatric Rating Scale (BPRS; Overall and Gorham, 1962). However, the PANSS has strict operational criteria for conducting the 30-40 minute patient interview, thorough definitions for all 30 items and detailed rating criteria for each level of psychopathology (Kay *et al.*, 1988). Seven of the items which represent productive features constitute the positive sub-scale; seven deficit items similarly constitute a negative syndrome sub-scale; and the remaining 16 which cannot be linked decisively to either syndrome serve as a general psychopathology sub-scale.

The psychometric properties of the PANSS have been studied extensively by the Kay group which developed the measure. Good inter-rater reliability (Kay *et al.*, 1988) adequate construct validity (Kay *et al.*, 1987, 1988), high internal reliability (Kay *et al.*, 1987), appropriate test-retest reliability (Kay *et al.*, 1987) and external validity (Kay *et al.*, 1986; 1987; Kay and Singh, 1989) have all been demonstrated. The most recent study (Opler *et al.*, 1994) replicated findings on the internal reliability of the PANSS, reporting α coefficients for the positive, negative and general psychopathology scales of 0.80, 0.82 and 0.82 respectively. An independent study (Bell *et al.*, 1992) has also established inter-rater reliability. The internal consistency coefficients for the positive negative and general psychopathology scales were 0.74, 0.69 and 0.64 respectively. Peralta and Cuesta (1994)

argue that the PANSS may be the most valuable instrument for clinical research in schizophrenia.

The PANSS is the standard measure used in most drug trials of new antipsychotic agents (Beasley *et al.*, 1997; Marder *et al.*, 1997) and is increasingly being used in studies evaluating psychological interventions for schizophrenia (for example, Macpherson *et al.*, 1996a). It offers a number of scientific and practical advantages over measures such as the BPRS (Overall and Gorham, 1962) and the KGV (Krawiecka *et al.*, 1977). A structured clinical interview, guide and videotaped training are available. Items are clearly defined and there are detailed criteria for each level of symptom severity. Such a comprehensive package enables research workers to be easily trained to perform very accurate and consistent assessments of patients' psychopathology.

4.14 SECONDARY OUTCOME MEASURES

4.14.1 Global Assessment of Functioning (GAF; Endicot *et al.*, 1976)

The Global Assessment of Functioning (GAF) is a quick and simple measure of overall psychological disturbance, which has been extensively used in studies evaluating pharmacological interventions (Gomez *et al.*, 2000; Schulzet *et al.*, 1999; Percudani *et al.*, 1999). The GAF consists of nine behavioural descriptors ranging from "absent or minimal symptoms (e.g. mild anxiety before an exam)" ... "no more than everyday problems" to "persistent danger of severely hurting self or others" ... "or persistent inability to maintain minimal personal hygiene or serious suicidal act with clear

expectation of death". Patients are rated between 0 (most severe) and 100 (least severe). Jones *et al.* (1995) demonstrated satisfactory validity and reliability for the GAF.

4.14.2 Hogan Drug Attitude Inventory (DAI-30; Hogan *et al.*, 1993)

The Hogan Drug Attitude Inventory (DAI-30) is a 30-item self-report measure predictive of compliance in people with schizophrenia. Each statement is rated as being true or false. To minimise the possibility of acquiescence bias there are an equal number of items to be scored true and false. The measure produces a total score ranging from +30 to -30. A positive score is predictive of compliance, a negative score of non-compliance. Statements were selected from an original pool of 100 based on the item's ability to discriminate between compliant and non-compliant patients. The scale has been shown to have a degree of discriminative validity, with 89% agreement between the DAI and clinician rating of whether patients were compliant or non-compliant. The DAI-30 has frequently been used in previous studies to evaluate the effectiveness of compliance interventions (e.g. Kemp *et al.*, 1996; 1998).

4.14.3 Clinician rating of compliance (Kemp *et al.*, 1998)

An informant and observer rating of compliance on a seven point scale, ranging from 1 (complete refusal) to 7 (active participation in treatment). Concurrent validity has been established by correlating scores with the Hogan Drug Attitude Inventory (DAI-30; Hogan *et al.*, 1983; Kemp *et al.*, 1998).

4.14.4 Expanded Schedule for the Assessment of Insight (SAI-E; Kemp and David 1997)

The expanded schedule for the assessment of insight is a ten-item researcher rated scale. Items are rated on a three-point scale based on a mental state examination (such as the structured clinical interview) and specific additional questions described in the measure. Scores are expressed as a percentage of total insight. The schedule has been used in previous trials (Kemp *et al.*, 1996; 1998; Macpherson *et al.*, 1996a) and satisfactory reliability and validity have been reported (Kemp and David, 1997).

4.14.5 Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS; Day *et al.*, 1995)

The LUNSERS is a 51-item self-report measure of the side effects of antipsychotic medication. Forty-one items covering psychological, neurological, autonomic, hormonal and miscellaneous side effects were constructed by rephrasing items from the UKU adverse events measure (Lingjaerde *et al.*, 1987) so that they could be self-rated. The remaining ten items were "red herrings" referring to symptoms which were not known antipsychotic side effects (e.g. hair loss). Each item is rated on a 5-point scale ranging from 'not at all' to 'very much' based on how frequently the patient has experienced the side effect in the last month.

The LUNSERS is an efficient, reliable and valid method of monitoring antipsychotic side effects. Day *et al.* (1995) showed good test re-test reliability (r=0.81) and concurrent validity against the UKU (r=0.83). It has also been demonstrated that there is a significant

but weak correlation between increasing doses of antipsychotic medication (measured in chlorpromazine equivalent) and the number and frequency of side effects measured using the LUNSERS (r=0.31; Day *et al.*, 1995).

4.14.6 Demographic information

Using a satadardised form constructed for this study age, gender, ethnicity, diagnosis and duration of illness were collected from patients' medical notes at the baseline assessment and confirmed with the patient at interview (appendix 12). It was assumed that demographic information would not change dramatically over the duration of the trial.

4.14.7 Prescribing information

All the medication that patients were prescribed on the day of assessment was recorded on a form (appendix 13). Data were recorded from the patient's drug chart and were crosschecked with the CPN and patient. Data were also obtained on whether the patient was receiving any non-pharmacological or alternative treatments such as Cognitive Behavioural Therapy (CBT).

4.14.8 Number of inpatient bed days

At each visit the researcher recorded, from the patient's medical notes, the number of days spent as an inpatient in the previous six months (appendix 14).

4.15 ETHICAL ISSUES

Ethical approval for this study was granted by local research ethics committees (LRECs) at the two study sites who reviewed the trial protocol.

4.16 STATISTICAL ANALYSIS

Parametric tests were used for most of the analyses, as the data were normally distributed (histograms for baseline scores for all the primary and secondary outcome measures are shown in appendix 15) and most of the measures used in the trial produced interval data which is well suited to such analysis. Even when supported by a specific hypothesis, all statistical tests performed were two tailed at a significance level of 0.05. The data were analysed in three ways:

- **Analysis of mean scores.** Mean scores were compared within and between groups. The t-test was used for analysing within group changes. An analysis of co-variance (ANCOVA) was used for between group comparisons of mean response to training. The ANCOVA was selected because it avoids repeated significance testing (thus reducing the risk of type I error), provides a simple clear summary of the response to training, and takes into account variations in pre-training scores.
- **Categorical change.** Analysis of mean scores can be a less useful determinant of outcome than percentage response rate if there is the potential for variation in response between subjects. A major component of the analysis therefore involved categorical change. Within group changes were analysed with the McNemar test and between group comparisons were analysed using the chi-square test or Fisher's exact test for small expected numbers. As the primary aim of this trial was to improve

patients' psychopathology, the determinant of outcome was the percentage of CPNs whose patients showed a mean 10% reduction in total PANSS scores.

- **Clinically significant change.** Clinically significant change was also analysed within and between groups. This was determined using Jacobson and Traux's (1991) criteria that a patient's post-treatment and follow-up scores extend to 2 standard deviations beyond the pre-treatment mean score. The analysis of clinically significant change was chosen because statistical significance offers little insight into the benefits of a training intervention in the real world. Clinical significance tends to make treatments look less effective than standard statistical comparisons imply (Jacobson *et al.*, 1988). Clinically significant change has not been reported in any of the previous trials of compliance or training interventions.

SPSS version 8.0 was used for all statistical analyses.

4.17 TRAINING AND TREATMENT FIDELITY

Revised training and treatment manuals (appendix 2 and 3) were written for this trial incorporating the results of the pilot study and feedback from trainees and trainers as well as the trial steering committee. The training for CPNs to equip them with the necessary skills to deliver the medication management intervention was broadly similar to the model described in the pilot study (chapter 3), but with some amendments. Increased time was devoted to practising each of the medication management interventions using a variety of role-play techniques. There was also increased emphasis on clinical supervision during and after the course to enhance fidelity to treatment.

Each of the CPNs who participated in the trial received peer group supervision, for the six-month duration of the intervention, with a clinician who was experienced in using medication management techniques.

4.18 CLINICIAN OUTCOME MEASURES

In order to establish CPNs' ability to deliver the medication management intervention, measures of knowledge and clinical skills were performed pre-, during- and post-training (Table 4.3). The procedures used to assess clinicians were as described in chapter 3.

Table 4.3. Timing of clinician assessments

Measure	Pre-training	Mid-training	Post-training
Demographics	●		
Knowledge about Medication Management Questionnaire	●		●
Cognitive Therapy Scale	●		●
Ability of trainees to assess patients' mental state		●	
Satisfaction with training			●

● = assessment

CHAPTER 5: RESULTS

5.1 PATIENT FLOW

Following a recruitment campaign in the two NHS Trusts participating in the trial, sixty CPNs who met the inclusion criteria, were recruited, and organised into geographical groups and randomised. Prior to recruiting patients eight CPNs withdrew from the trial, 3 in the experimental group and 5 in the control group. Four had found alternative employment in a different NHS Trust and two withdrew because they reported that they were too busy to attend the training. Fifty-two CPNs entered the trial and referred 89 patients who were assessed by the research worker. Seven patients did not meet the inclusion/exclusion criteria. Of these, five had not been diagnosed as suffering from a psychotic disorder or were not prescribed or recommended to take antipsychotic medication and two were not on the caseload of the CPN who referred them. A total of 82 patients were eligible for inclusion in the trial. Of these, five (6%) refused to participate, three gave no reason and two said they did not want to participate in a research project. Seventy-seven patients gave written consent and entered the study, a mean of 1.48 per CPN.

5.2 PATIENT DROP-OUTS

Of the 77 patients who entered the trial 8 (10%) left the caseload of the CPN who was treating them, three prior to the week 26 and 5 prior to the week 52 assessments and were classified as training drop-outs (table 5.1a). Three of the non-completers were from the experimental group and five from the control (this difference was not significant). The reported reasons for patients dropping out of the trial did not appear to be related to the

study. Six patients moved out of the geographical area covered by the CPN treating them, one could not be traced and had also, presumably, moved out of the area and one was sent to prison and their care was transferred to a forensic psychiatric team.

Table 5.1.a Number of patient drop-outs by group

	Baseline	Week 26	Week 52
Experimental	0	1	2
Control	0	2	3

5.3 CPN DROP-OUTS

Of the 52 CPNs who entered the study eight withdrew before the end of the trial, two before the week 26 and 6 before the week 52 assessments (table 5.1b). Three were from the experimental and five from the control group (this difference was not significant). Seven CPNs left the NHS Trust and one was promoted and withdrew from clinical work. If CPNs dropped out of the trial their patients were classified as drop-outs.

Table 5.1.b Number of CPN drop-outs by group

	Baseline	Week 26	Week 52
Experimental	0	1	2
Control	0	1	4

In total twenty patients dropped out of the trial. Fifty-seven patients (74%) were on the caseloads of the CPNs at the end of the trial and were defined as completers. Not all of the patients that finished the trial completed all the assessments.

5.4 COMPLETED ASSESSMENTS

Fifty-one patients (66%) were assessed at week 26 and thirty-five (45%) at week 52. Assessments were not completed because some patients refused to be interviewed (but did not drop out of the trial) or the assessment could not be organised within the four-week window allowed within the trial protocol. Two patients did not want to be interviewed by the research worker but agreed to complete and return their self-rated measures by post.

Complete data are presented for 52 trainees at baseline (27 in the experimental and 25 in the control group), 42 at the week 26 assessment (23 in the experimental and 19 in the control group) and 29 at the week 52 assessment (15 in the experimental and 14 in the control group).

5.5 CPN PRE-TRAINING CHARACTERISTICS

Pre-training variables in each training group were compared using the chi-square test (reported with continuity correction, or Fisher's exact test) for categorical or dichotomous variables. Continuous variables were compared using an independent samples t-test. All tests were two-tailed.

5.5.1 Demographic variables (table 5.2)

Among the 52 CPNs who entered the trial there were more men than women, the majority were of white ethnic origin with a mean average age of 39 years. The majority of CPNs held senior clinical grades, were experienced clinicians, and were educated to at least diploma level. There were no significant differences between the two groups except that CPNs in the experimental group were more clinically experienced.

Table 5.2. Demographic characteristics of trainees. Demographic characteristics of CPNs who completed week 26 and week 52 assessments and the generic community mental health nurse sample from the 4th Quinquennial census (Brooker and White 1997) are presented for comparison.

		Experimental group			Control group			
		Wk. 0 (n=27)	Wk. 26 (n=23)	Wk. 52 (n=15)	Wk. 0 (n=25)	Wk. 26 (n=19)	Wk. 52 (n=14)	4th QC sample
Gender	Male	10 (37%)	9 (39%)	9 (60%)	13 (52%)	8 (42%)	5 (36%)	43%
	Female	17 (63%)	14 (61%)	6 (40%)	12 (48%)	11 (58%)	9 (64%)	57%
Age in years (s.d.)		39 (8.3)	40.2 (8.5)	41.6 (6.5)	38 (7.7)	36.9 (7.5)	35.8 (7.7)	39
Ethnicity	White	13 (48%)	11 (48%)	7 (47%)	10 (40%)	7 (37%)	5 (36%)	90%
	Black	6 (22%)	4 (17%)	4 (27%)	10 (40%)	7 (37%)	5 (36%)	3%
	Asian	8 (30%)	8 (35%)	4 (27%)	4 (16%)	5 (26%)	4 (29%)	6%
	Other	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)	1%
Experience in yrs (s.d.)		10.9 (6.6)	11.1 (6.8)	11.0 (6.7)	5.6 (3.9)	6.25 (5.01)[1]	6.8 (5.4)	14
Grade	D	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1%
	E	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	14%
	F	8 (30%)	5 (22%)	3 (20%)	10 (40%)	8 (42%)	6 (43%)	13%
	G	19 (70%)	18 (78%)	12 (80%)	12 (48%)	8 (42%)	8 (57%)	61%
	H	0 (0%)	0 (0%)	0 (0%)	3 (12%)	3 (16%)	0 (0%)	9%
	I	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2%
Highest quali.	Cert.	13 (48%)	10 (43%)	6 (40%)	13 (52%)	13 (68%)	9 (64%)	No data
	Dip.	7 (26%)	6 (26%)	4 (27%)	6 (24%)	5 (26%)	5 (36%)	
	BSc/BA	7 (26%)	7 (30%)	5 (33%)	4 (16%)	1 (5%)	0 (0%)	
	Masters	0 (0%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)	
Case-load (s.d)		35.7 (8.3)	33.6 (8.6)	35.4 (8.6)	34.6 (9.3)	33.6 (9.8)	36 (2.8)	38.3

[1] significant difference found between the groups at week 0 assessment (p=.002)

5.5.2 CPN Pre-training scores on main and secondary outcome measures (table 5.3)

Pre-training CTS total scores were at the low end of the 0-60 scoring range, indicating that CPNs' general cognitive and specific compliance therapy skills were poor. Scores on the Knowledge about Medication Management Questionnaire were in the middle of the 0-16 range suggesting a moderate level of understanding about the use of medication management interventions.

Table 5.3. CPN mean (s.d.) pre-training scores by group

	Experimental	Control
CTS total score[1]	12.3 (4.1)	15.8 (3.6)
Knowledge about Medication Management Questionnaire	8.8 (2.0)	9.2 (2.3)

[1] Significant difference found between the two groups (p=.004)

CPNs in the experimental group had significantly lower scores on the Cognitive Therapy Scale at the pre-training assessment. There were significant differences between the two groups for items one (agenda setting; p=.016) and six (pacing and efficient use of time; p=.023).

5.5.3 Comparisons between CPNs who completed, withdrew and dropped out of the trial

Pre-training characteristics of CPNs who entered and those who withdrew before the start of the trial were compared. No significant differences were found on any of the following

variables: age, gender, ethnicity, years of experience, grade, highest academic achievement, or case-load size. The demographic profile of trainees who completed the week 26 assessment is no different to CPN characteristics at baseline. The same is true at the week 52 assessment.

5.6 ANALYSIS OF CPN OUTCOMES

The dependent variables were three measures of CPNs' clinical skills and knowledge. The primary CPN outcome measure (used to define overall improvement in clinical skill) was a video-taped role-play session blind rated using the Cognitive Therapy Scale (Vallis *et al.*,1986; Dobson *et al.*, 1985). The main secondary outcome measures (detailed in chapter 4) were as follows:

1. The Knowledge about Medication Management Questionnaire.
2. The CPNs' reliability (using the Positive and Negative Syndrome scale) in rating a video of a patient being interviewed using the structured clinical interview.
3. A trainee satisfaction questionnaire.

Higher scores indicate improvements in trainees' skills, knowledge and satisfaction with training.

5.6.1 Statistical analyses

To identify within group differences post-training, paired t-tests were used (two-tailed). The McNemar test was used to examine changes in the proportion of trainees who achieved a satisfactory score on the CTS post-training.

5.6.2 Changes in mean scores on the CTS (table 5.4)

Table 5.4 shows mean total and item scores for the CTS. Highly significant improvements in both CTS total and item scores were found.

Table 5.4. Changes in mean (s.d.) item and total scores on the Cognitive Therapy Scale pre- and post-training

	Experimental (n=25) Training administered following baseline assessment			Control (n=23) Training administered following week 26 assessment		
CTS item	**Pre-training** Mean (s.d.)	**Post-training** Mean (s.d.)	**p**	**Pre-training** Mean (s.d.)	**Post-training** Mean (s.d.)	**p**
Agenda setting	0.6 (0.8)	3.0 (.7)	<.001	1.3 (1.0)	2.9 (1.2)	<.001
Feedback	1.1 (1.1)	3.2 (1.1)	<.001	1.7 (1.1)	3.2 (0.9)	<.001
Understanding	1.3 (0.9)	3.4 (1.2)	<.001	1.1 (0.7)	3.2 (0.8)	<.001
Interpersonal effectiveness	1.6 (0.8)	3.1 (1.2)	<.001	1.7 (1.0)	3.1 (1.1)	<.001
Collaboration	1.4 (1.0)	2.9 (1.3)	<.001	1.8 (0.9)	3.1 (1.5)	=.002
Pacing and efficient use of time	1.0 (0.9)	3.3 (1.1)	<.001	1.6 (0.9)	3.0 (0.9)	<.001
Guided discovery	1.3 (0.7)	3.4 (0.9)	<.001	1.5 (0.9)	3.3 (1.4)	<.001
Strategy for change	1.2 (0.9)	3.3 (1.2)	<.001	1.6 (1.0)	3.0 (1.1)	<.001
Application of medication management techniques	1.3 (0.7)	3.0 (0.8)	<.001	1.6 (0.9)	2.6 (1.2)	=.004
Clinician rating	1.5 (0.9)	2.8 (0.9)	<.001	1.7 (0.8)	2.8 (0.9)	<.001
Total score	**12.3 (4.1)**	**31.6 (5.4)**	<.001	**15.8 (3.7)**	**30.5 (6.0)**	<.001

Pre-training, none of the trainees demonstrated satisfactory skills on the CTS. Post training 14 (56%) in the experimental and 10 (43%) in the control group achieved this standard (table 5.5). Significant improvements in the proportion of trainees who achieved a satisfactory standard on the CTS items were also found. The difference between the two groups in the number of trainees who achieved a satisfactory standard was not statistically significant.

Table 5.5. Proportion of trainees who achieved a satisfactory standard on the Cognitive Therapy Scale pre- and post-training

	Experimental (n=25) Training administered following baseline assessment			Control (n=23) Training administered following week 26 assessment		
CTS item	**Pre-training**	**Post-training**	**p**	**Pre-training**	**Post-training**	**p**
Agenda setting	0 (0%)	17 (68%)	<.001	2 (9%)	14 (61%)	<.001
Feedback	3 (12%)	17 (68%)	<.001	4 (17%)	16 (70%)	=.002
Understanding	2 (8%)	15 (60%)	<.001	0 (0%)	18 (78%)	<.001
Interpersonal effectiveness	3 (12%)	17 (68%)	<.001	5 (22%)	14 (61%)	=.035
Collaboration	3 (12%)	12 (48%)	=.012	5 (22%)	15 (65%)	=.007
Pacing and efficient use of time	0 (0%)	18 (72%)	<.001	4 (17%)	16 (70%)	=.002
Guided discovery	1 (4%)	19 (76%)	<.001	1 (4%)	18 (78%)	<.001
Strategy for change	2 (8%)	15 (60%)	<.001	4 (17%)	11 (48%)	=.039
Application of medication management techniques	0 (0%)	16 (64%)	<.001	3 (13%)	11 (48%)	=.021
Clinician rating	3 (12%)	17 (68%)	=.001	2 (9%)	13 (57%)	=.001
Total score	**0 (0%)**	**14 (56%)**	<.001	**0 (0%)**	**10 (43%)**	**=.008**

5.6.3. Changes in mean scores on the Knowledge about Medication Management Questionnaire (table 5.6)

Significant improvements in trainees' knowledge were found from pre- to post-training assessment.

Table 5.6. Changes in mean (s.d.) total scores on the Knowledge about Medication Management Questionnaire pre- and post-training

	Experimental (n=25) Training administered following baseline assessment			Control (n=23) Training administered following week 26 assessment		
	Pre-training	Post-training	p	Pre-training	Post-training	p
	Mean (s.d.)	Mean (s.d.)		Mean (s.d.)	Mean (s.d.)	
Knowledge about Medication Management Questionaire total score	8.8 (2.0)	12.5 (2.2)	=.008	9.2 (2.3)	12.3 (2.5)	=.001

5.6.4 Mental state assessment

Twenty-nine (60%) trainees rated the video of a patient being interviewed to a satisfactory standard. The mean number of errors (items not rated to within $\pm$ 1 point of the gold standard) per trainee was 6.2 out of 30 (21%). No significant differences in trainees' concordance with the gold standard were observed between positive symptoms (mean 1.8 errors) negative symptoms (mean 2.3 errors) and general psychopathology (mean 2.1 errors).

5.6.5 Ratings of CPN satisfaction with training (appendix 16)

Trainees reported that they were either very satisfied or satisfied with the content of the course and the quality of the teaching. They also reported that they were able to apply the skills they had learnt to the patients on their caseload.

5.7 PREDICTION OF CHANGE

Exploratory stepwise linear regression was used to identify factors predictive of trainees' knowledge and skill following training in both groups combined. Post-training scores on the CTS and the Knowledge about Medication Management Questionniare were the dependent variables. Baseline scores were entered first and then the following variables were entered on the second level using stepwise procedures: Trainees' caseload size, experience, clinical grade, highest academic qualification and attendance.

A model that included trainees' highest academic qualification, grade and attendance was predictive of CTS scores post-training. Baseline scores alone accounted for 67% of the variance in CTS scores (R^2=.67, F=109.34, p<.001). Highest academic qualification, grade and attendance accounted for an additional 29% of the variance (R^2=.98 (adjusted R^2=.96), F=71.18, p<.001).

Baseline scores on the Knowledge about Medication Management Questionaire were predicative of trainees' knowledge post-training (R^2=.909, F=109.3, P<.001). No other significant predictors emerged.

5.8 PATIENT CHARACTERISTICS AT BASELINE ASSESSMENT

Patients' demographic and clinical characteristics and medication usage are presented in their raw form and have not been averaged. The demographic profile of patients who completed week 26 and week 52 assessments are presented as a comparison to show that the two groups do not differ, taking into account drop-outs. Baseline variables in each training group were compared using the chi-square test (reported with continuity correction or Fisher's exact test) for categorical or dichotomous variables. Continuous variables were compared using independent sample t-tests. All statistical tests were two-tailed.

5.8.1 Demographic variables (table 5.7)

Of the 77 patients who entered the trial, men outnumbered women by about 2:1 and just over half classified themselves as being of white ethnic origin. They were middle aged and over half were not married or cohabiting. There was no significant difference in the demographic profile of the two groups.

Table 5.7. Demographic characteristics by group for patients who completed baseline (week 0), week 26 and week 52 assessments

		Experimental			Control		
		Wk. 0 (n=40)	Wk. 26 (n=27)	Wk. 52 (n=15)	Wk. 0 (n=37)	Wk. 26 (n=24)	Wk. 52 (n=20)
Gender	Male	29 (72%)	18 (67%)	10 (67%)	22 (59%)	17 (71%)	15 (75%)
	Female	11 (28%)	9 (33%)	5 (33%)	15 (41%)	7 (29%)	5 (25%)
Marital status	Single	25 (62%)	15 (55%)	9 (60%)	22 (60%)	16 (59%)	15 (75%)
	Married/ cohabiting	4 (10%)	3 (11%)	1 (7%)	3 (8%)	2 (8%)	0 (0%)
	Widowed/ separated/ divorced	11 (28%)	9 (33%)	5 (33%)	12 (32%)	6 (25%)	5 (25%)
Ethnicity	White	23 (58%)	16 (59%)	9 (60%)	22 (60%)	14 (58%)	9 (45%)
	Black	7 (17%)	4 (15%)	3 (20%)	3 (8%)	1 (4%)	2 (10%)
	Asian	8 (20%)	5 (19%)	2 (13%)	12 (32%)	9 (38%)	9 (45%)
	Other	2 (5%)	2 (7%)	1 (7%)	0 (0%)	0 (0%)	0 (0%)
Age in years (mean/s.d.)		41.4 (10.6)	44.2 (9.3)	43.4 (10.9)	39.5 (12.5)	40.3 (12.9)	39 (11.6)

5.8.2 Clinical characteristics (table 5.8)

The mean age of onset of illness was 27.6 (s.d. 10.7) years and patients had, on average, been ill for 13 (s.d. 9.7) years. All patients had been diagnosed with a psychotic mental illness and for the majority this was labelled as schizophrenia. Almost two-thirds of the patients smoked cigarettes and half reported that they drank alcohol. The majority of patients had had at least one previous psychiatric hospital admission, and over half of the patients had been detained in hospital on at least one occasion under a section of the mental health act. On average patients had been living in the community for over a year and almost two thirds were registered on the Care Programme Approach (CPA). There were no significant differences between the experimental and control groups on any of these characteristics although there was a trend towards a longer duration of illness in patients in the experimental group. There was also a trend in this group to having been living in the community for longer.

Table 5.8. Clinical characteristics by group for patients who completed baseline (week 0), week 26 and week 52 assessments

		Experimental			Control		
		Wk. 0 (n=40)	Wk. 26 (n=27)	Wk. 52 (n=15)	Wk. 0 (n=37)	Wk. 26 (n=24)	Wk. 52 (n=20)
Mean duration of illness (s.d.). In years		15.2 (9.6)	16.6 (9.9)	15.6 (10.8)	10.9 (9.5)	8.9 (10.1)	8.4 (6.5)
Age of onset in years (mean/s.d.)		25.5 (7.3)	26.6 (7.2)	26.1 (7.7)	29.5 (12.8)	31.8 (13.4)	30.8 (11.7)
Percentage of patients previously admitted to psychiatric hospital		33 (82%)	22 (81%)	13 (87%)	34 (92%)	22 (92%)	18 (90%)
Number of previous psychiatric admissions		2.8 (2.3)	2.9 (2.2)	3.6 (2.3)	3.2 (2.0)	3.0 (2.1)	3.2 (2.2)
Time since last admission in months (s.d.)		17.7 (10.7)	18.3 (8.6)	18.4 (10.8)	12.5 (12.9)	11.9 (12.7)	11.7 (12.3)
Diagnosis	Schizophrenia	33 (83%)	23 (85%)	13 (87%)	32 (87%)	21 (88%)	17 (85%)
	Schizoaffective	2 (5%)	1 (4%)	1 (7%)	2 (5%)	1 (4%)	1 (5%)
	Bi-polar	5 (12%)	3 (11%)	1 (7%)	3 (8%)	2 (8%)	2 (10%)
Smoke cigarettes		23 (58%)	14 (52%)	8 (53%)	22 (61%)	15 (63%)	15 (75%)
Drink alcohol		16 (41%)	11 (41%)	6 (40%)	18 (49%)	13 (54%)	9 (45%)
Registered on the Care Programme Approach (CPA)		35 (88%)	24 (89%)	13 (87%)	33 (89%)	22 (81%)	19 (95%)
Ever detained in hospital under the mental health act		21 (53%)	13 (48%)	9 (60%)	17 (46%)	11 (46%)	11 (55%)

5.8.3 Psychotropic medication usage (table 5.9)

Antipsychotic medication had been recommend by a Psychiatrist for all patients and was prescribed for the majority. Patients were receiving relatively high doses (in chlorpromazine equivalents) of antipsychotic medication and the majority had been taking it for at least 3 months. Half of the patients received their antipsychotic medication via a long acting depot preparation. Polypharmacy was common, as was the long-term prophylactic use of anticholinergic medication. Fourteen (18%) patients were treated with atypical antipsychotics (risperidone, olanzapine or quetiapine) and six (8%) patients were receiving clozapine therapy. A minority of patients were also prescribed antidepressants, mood stabilisers, and benzodiazapines. Patients' medication histories were often complex and difficult to quantify. Treatment with specialist non-pharmacological therapies (such as family work or CBT) was rare.

Again, there were no significant differences between the experimental and control groups on any of these characteristics.

Table 5.9. Medication at trial entry by group for patients who completed baseline (week 0), week 26 and week 52 assessments

	Experimental			Control		
	Wk. 0 (n=40)	Wk. 26 (n=27)	Wk. 52 (n=15)	Wk. 0 (n=37)	Wk. 26 (n=27)	Wk. 52 (n=20)
Treatment with antipsychotic medication recommended by Psychiatrist	40 (100%)	27 (100%)	15 (100%)	37 (100%)	27 (100%)	20 (100%)
Prescribed antipsychotic medication	35 (88%)	25 (93%)	14 (93%)	33 (89%)	25 (93%)	18 (90%)
Mean dose (mg) per day of antipsychotic in chlorpromazine equivalents (s.d.)*	418 (312)	372 (278)	554 (234)	480 (253)	510 (278)	513 (298)
Duration of treatment with current antipsychotic medication (percentage greater than three months)	31 (78%)	23 (85%)	12 (80%)	27 (73%)	20 (83%)	18 (90%)
Antipsychotic administered via depot	21 (62%)	15 (56%)	9 (60%)	15 (41%)	10 (42%)	10 (50%)
Patient receiving an atypical antipsychotic	6 (15%)	3 (11%)	3 (20%)	8 (22%)	6 (25%)	5 (25%)
Patient receiving clozapine therapy	4 (10%)	2 (7%)	1 (4%)	2 (5%)	0 (0%)	0 (0%)
Mean number of antipsychotics per patient (s.d.)	1.1 (.61)	1.2 (.61)	1.2 (.56)	1.2 (.63)	1.3 (.46)	1.3 (.56)
Prescribed anticholinergic medication	20 (50%)	14 (52%)	8 (53%)	19 (51%)	13 (54%)	10 (50%)
Prescribed antidepressant medication	6 (15%)	4 (15%)	2 (13%)	7 (19%)	4 (17%)	4 (20%)
Prescribed a mood stabiliser	7 (18%)	3 (11%)	2 (13%)	4 (11%)	1 (4%)	1 (5%)
Prescribed benzodiazapines	3 (8%)	1 (4%)	1 (7%)	2 (5%)	1 (4%)	0 (0%)
Family work	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Cognitive behavioural therapy (CBT)	3 (8%)	2 (7%)	1 (7%)	2 (5%)	1 (4%)	1 (5%)

*Chlorpromazine equivalence data is not available for some atypical antipsychotics

5.9 BASELINE SCORES ON PRIMARY AND SECONDARY OUTCOME MEASURES (Tables 5.10 and 5.11)

Scores on primary and secondary outcome measures are presented with the CPN as the unit of analysis. Trainee scores are the mean of the two patients they were treating. Mean total and sub-scale scores on the PANSS (table 5.10) at baseline suggest that CPNs' patients were experiencing a moderate level of psychopathology.

Table 5.10. Baseline mean (s.d.) scores by group for patients who completed the primary outcome measure at baseline (week 0), week 26, and week 52 assessments

	Experimental			Control		
	Wk. 0 (n=27)	Wk. 26 (n=23)	Wk. 52 (n=15)	Wk. 0 (n=25)	Wk 26 (n=19)	Wk 52 (n=14)
PANSS total score	72.5 (11.9)	74.8 (14.5)	73.8 (13.2)	66.5 (10.7)	66.2 (10.2)	65.0 (9.6)
Positive sub-scale	17.4 (5.5)	18.9 (5.8)	17.7 (4.6)	16.9 (3.9)	17.1 (3.4)	16.8 (3.7)
Negative sub-scale	18.3 (5.1)	18.1 (4.4)	18.8 (4.5)	16.6 (4.3)	15.7 (3.6)	15.8 (3.2)
General psychopathology sub-scale	36.5 (7.2)	37.3 (7.8)	37.4 (7.0)	33.0 (6.9)	33.4 (6.6)	32.4 (6.4)

Baseline mean scores for secondary outcome measures are shown in table 5.11. Baseline scores on the GAF suggest a moderate level of impairment. No significant differences were found between groups. Scores, at baseline, on the DAI-30 were in the middle of the

range of scores produced by the measure and suggests that patients were ambivalent about treatment with antipsychotic medication. These findings are consistent with the observer ratings of compliance which were also in the middle of the scale and suggests that patients were reluctant to take, or regularly questioned the need for, medication. Scores on the insight schedule were at the lower end of the percentage scale and suggest that patients' insight was markedly impaired. Mean scores on the LUNSERS were at the low and of the scale suggesting that patients were reporting some antipsychotic side effects. No significant differences between the groups were found.

Table 5.11. Baseline mean (s.d.) scores by group for patients who completed secondary outcome measures at the baseline (week 0), week 26 and week 52 assessments

	Experimental			Control		
	Wk. 0 (n=27)	Wk. 26 (n=23)	Wk. 52 (n=15)	Wk. 0 (n=25)	Wk 26 (n=19)	Wk 52 (n=14)
Global Assessment of Functioning	53.0 (7.7)	52.2 (7.7)	54.6 (9.3)	58.3 (8.4)	59.2 (4.6)	59.2 (4.6)
Drug Attitude Inventory	0.4 (9.8)	-1.3 (9.9)	4.1 (7.1)	2.7 (10.6)	3.4 (11.2)	3.7 (12.4)
Composite measure of compliance	4.0 (0.9)	3.8 (0.9)	4.2 (0.7)	4.3 (1.3)	4.3 (1.4)	4.2 (1.5)
Schedule for the Assessment of Insight-Expanded	36.6 (22.1)	35.2 (18.7)	51.9 (10.9)	53.2 (19.7)	54.6 (16.2)	54.6 (16.3)
Liverpool University Neuroleptic Side Effect Rating Scale	35.5 (22.5)	33.2 (24.5)	17.0 (12.8)	26.4 (9.7)	24.1 (6.1)	24.1 (6.2)

5.10 COMPARISONS BETWEEN TRIAL COMPLETERS, TRIAL REFUSERS, AND TRIAL DROP-OUTS ON PRE-TRAINING VARIABLES

Baseline characteristics of patients entering the trial and those who refused to participate were compared. No significant differences were found on any of the following variables: age, gender, ethnicity, employment status, marital status, duration of illness, number of previous psychiatric admissions, or dose of antipsychotic medication. As tables 5.7-5.11 show there was no difference in the baseline demographic and clinical profile of patients who entered the trial or completed the week 26 or week 52 assessment. This suggests that patients dropped out of the trial by chance.

5.11 ANALYSIS OF PATIENT OUTCOME

5.11.1 Primary and secondary outcome measures

The dependent variables comprised three research worker, two patient and one CPN rated outcome measures and their sub-scales. Prescribing data were recorded by the research worker from the patient's drug chart and checked with the CPN and patient. The primary outcome measure (used to define overall improvement in patients' psychopathology) was the Positive and Negative Syndrome Scale (PANSS), a thirty item scale divided into three sub-scales (positive, negative and general psychopathology). Each item is rated on a 1-7 scale. Secondary outcome measures (detailed in chapter 4) were as follows:

1. Disability – The Global Assessment of Functioning disability scale (range 0-100) with 10 defined anchor points relating to social competence.
2. Compliance – The Drug Attitude Inventory (range -30 to +30); Observer rating of compliance (range 1-7).

3. Insight – Expanded schedule for the assessment of insight. Scores expressed as a percentage of insight.
4. Side effects – Liverpool University Neuroleptic Side Effect Rating Scale (total score range 0-164 excluding red-herrings). Eight sub-scores; extrapyramidal (range 0-28); anticholinergic (0-20); other autonomic (0-20); allergic (0-16); psychic (0-40); hormonal (0-24); miscellaneous (0-16); and red herrings (0-40).
5. Prescribed medication – The chlorpromazine equivalent dose (in mg per day) of antipsychotic was the main measure of prescribing.
6. Service utilisation – Measured in the number of psychiatric inpatient days during the previous 26 weeks.

5.11.2 Statistical analyses

Data were normally distributed and parametric tests were therefore used for most of the analyses. Outcome data were analysed in two ways. Firstly, between and within group changes in mean scores were analysed. Secondly, levels of categorical and clinically significant change were analysed within and between groups.

In this trial, as in previous training studies, some CPNs and patients did not complete the trial. Both CPN and patient drop-outs were evenly distributed between training groups and did not significantly differ from completers on any pre-training characteristics or scores. It may be acceptable to restrict the analysis to trainees for whom complete data is available (Everitt and Pickles, 2000). Alternatively Pocock (1983) proposes conducting

two analyses: one for trial completers alone, and a second analysis which, where possible, includes data for all subjects (intention to treat).

Intention to treat analysis is difficult when a quantitative measurement is the basis of evaluation. In such cases, a common practice is to bring forward the last known value as a substitute for data missing at later dates. This method has been criticised, chiefly for the assumption that a patient's response remains frozen in time (Everitt, 1998). Nevertheless this remains the most widely used and conservative method of managing the problem of trial drop-outs.

The inclusion of drop-outs in analyses of qualitative outcome is less contentious. In the analyses of categorical change and clinical significance, non-completers were categorised as non-responders.

5.11.3 Changes in mean scores

The mean scores and standard deviations on all outcome measures and sub-scales at all time points for both the experimental and control groups can be found in tables 5.12a-c.

Graphs of the mean scores by training group on primary and secondary outcome measures for both groups are shown in figure 5.1.

Table 5.12.a Mean scores and standard deviations for experimental and control groups on primary and secondary outcome measures

Measure	Experimental group (CPNs trained after baseline assessment)		Control group (CPNs trained after week 26 assessment)	
	Mean	s.d.	Mean	s.d.
PANSS-total[1]				
Baseline	72.5	11.9	66.5	10.7
Week 26	57.6	9.1	60.2	11.45
Week 52	56.8	4.8	56.8	4.8
GAF[1]				
Baseline	53.0	7.7	58.3	8.4
Week 26	56.5	9.7	65.4	73.2
Week 52	64.7	10.1	73.2	14.7
DAI-30[2]				
Baseline	0.4	9.8	2.7	10.6
Week 26	9.0	9.5	6.66	11.8
Week 52	9.8	9.1	9.2	10.0
Compliance[2]				
Baseline	4.0	0.88	4.3	1.3
Week 26	5.2	0.83	3.8	1.1
Week 52	4.8	0.75	4.8	1.2
SAI-E[2]				
Baseline	36.6	22.1	53.18	19.7
Week 26	43.5	10.8	47.1	21.8
Week 52	39.7	8.8	54.5	14.4
LUNSERS-total[1]				
Baseline	35.5	22.5	26.4	9.7
Week 26	27.4	22.1	21.1	9.8
Week 52	31.1	20.4	25.5	8.4
Dose mg/day (cpz. equ.)[1]				
Baseline	400	317	469	293
Week 26	387	253	479	237
Week 52	383	239	456	259
Service utilisation[1]				
Week 26	7.5	13.6	13.0	25.1
Week 52	13.3	20.2	11.0	12.3

[1] reduction in scores suggests improvement [2] increase in scores indicates an improvement

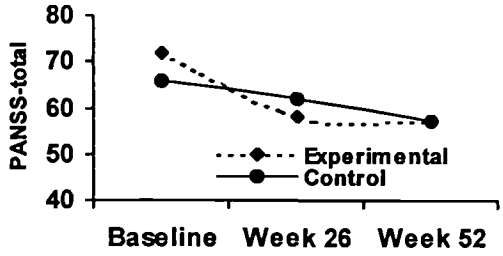
5.12b Mean scores and standard deviations for experimental and control groups on PANSS sub-scales

Measure	Experimental group (CPNs trained after baseline assessment)		Control group (CPNs trained after week 26 assessment)	
	Mean	s.d.	Mean	s.d.
PANSS-positive sub-scale				
Baseline	17.4	5.5	16.9	3.9
Week 26	14.9	4.3	14.3	4.2
Week 52	14.3	3.5	11.8	4.4
PANSS- negative sub-scale				
Baseline	18.3	5.1	16.6	4.3
Week 26	14.2	2.7	14.0	3.7
Week 52	12.7	2.8	10.9	2.9
PANSS-general sub-scale				
Baseline	36.5	7.2	33.0	6.9
Week 26	28.6	4.4	32.2	6.7
Week 52	29.7	2.8	25.3	4.9

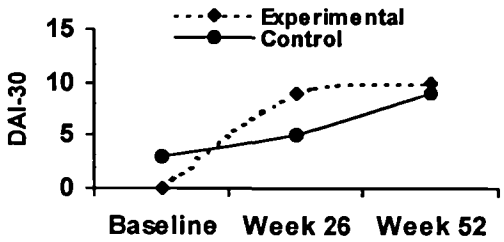
5.12c Mean scores and standard deviations for experimental and control groups on LUNSERS sub-scales

Measure	Experimental group (CPNs trained after baseline assessment)		Control group(CPNs trained after week 26 assessment)	
	Mean	s.d.	Mean	s.d.
LUNSERS - EPS sub-scale				
Baseline	10.8	5.7	8.2	3.9
Week 26	11.2	6.1	6.0	3.8
Week 52	12.5	5.3	6.8	3.8
LUNSERS – anticholinergic sub-scale				
Baseline	6.1	1.7	4.3	2.0
Week 26	6.1	2.1	3.3	1.9
Week 52	5.4	2.9	3.7	2.2
LUNSERS – autonomic sub-scale				
Baseline	1.3	2.1	0.4	0.56
Week 26	1.4	2.1	2.5	2.5
Week 52	0.9	1.0	2.0	1.9
LUNSERS – allergic sub-scale				
Baseline	2.2	1.8	3.1	2.8
Week 26	2.0	2.0	2.4	2.6
Week 52	2.8	2.8	2.8	2.7
LUNSERS – Psychic sub-scale				
Baseline	12.3	11.4	12.2	5.6
Week 26	10.0	12.7	8.0	7.9
Week 52	11.4	8.2	12.4	5.4
LUNSERS – Hormonal sub-scale				
Baseline	2.2	4.4	2.0	2.7
Week 26	2.1	3.9	0.9	1.4
Week 52	3.1	4.4	0.8	1.1
LUNSERS – Miscellaneous sub-scale				
Baseline	3.6	2.3	4.1	2.0
Week 26	4.3	1.4	3.6	1.1
Week 52	5.5	1.9	3.8	0.96
LUNSERS – Red herrings sub-scale				
Baseline	4.4	2.8	4.2	2.5
Week 26	5.1	2.7	3.5	2.0
Week 52	6.6	3.7	4.0	2.0

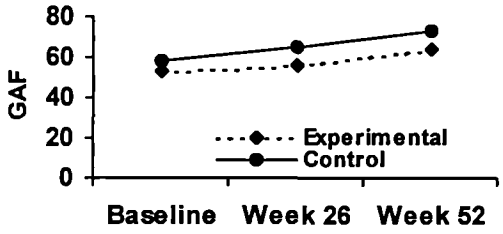
Positive and negative syndrome scale (PANSS) total



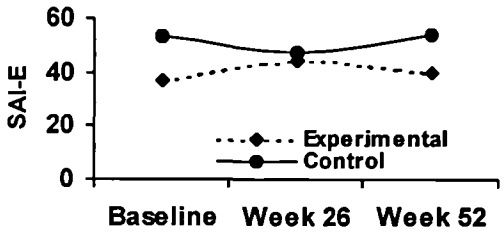
Hogan drug attitude inventory (DAI-30)



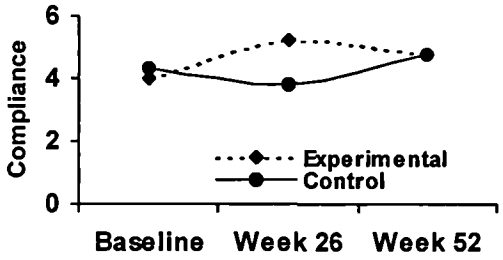
Global assessment of functioning (GAF)



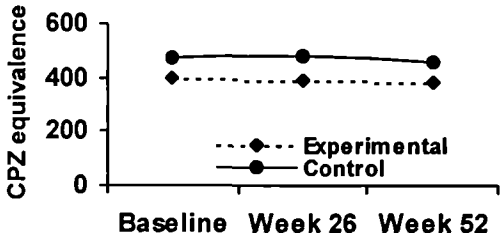
Expanded schedule for the assessment of insight (SAI-E)



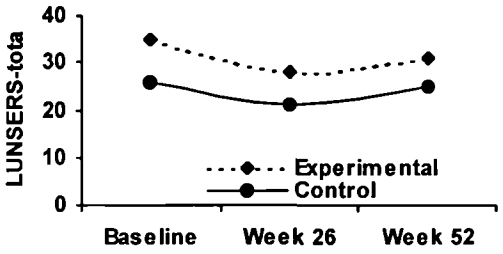
Clinician rating of compliance



Chlorpromazine equivalent dose of antipsychotic



Liverpool University Neuroleptic Side Effect Rating Scale



5.11.4 Was there a difference between the experimental and control groups at the week 26 assessment?

An ANCOVA showed that care from CPNs who had undergone medication management training was superior to CPNs' routine care on the primary measure of clinical outcome, the Positive and Negative Syndrome Scale ($F=5.54$, $df=1$, $p=.026$). Training was also superior on two secondary outcome measures, the Drug Attitude Inventory ($F=16.76$, $df=1$, $p<.001$) and clinician rating of compliance ($F=28.52$, $df=1$, $p<.001$). There was no significant difference between the groups on the Global Assessment of Functioning, the Expanded Schedule for the Assessment of Insight, the dose of prescribed antipsychotic or the LUNSERS. Care by CPNs who had received medication management training was not superior to routine CPN care over time on any of the PANSS sub-scales. There was a trend towards a difference in the EPS ($p=.057$) and red-herring ($P=.063$) sub-scales of the LUNSERS.

An ANCOVA for the primary and secondary outcome measures was repeated using data from all patients: trial drop-outs were assigned their last known value at all subsequent time points. The same pattern of results was found on all main outcome measures. Medication management training was superior to standard CPN care over time on measures of psychopathology ($F=4.79$, $df=1$, $p=.036$), attitudes towards treatment ($F=14.84$, $df=1$, $p=.001$) and compliance ($F=28.50$, $df=1$, $p<.001$) but not functioning, insight or side effects.

5.11.5 What was the effect of training in the experimental group (baseline to week 26)?

From baseline to week 26 assessment there were significant improvements in the primary measure of patients' psychopathology (PANSS-total; t=6.87, df=22, p<.001). Significant improvements in patients' attitudes towards treatment (DAI-30; t=-49, df=22, p<.001) and compliance (t=-7.09, df=22, p<.001) were also found.

5.11.6 Was the effect of training sustained at the follow-up (week 52) assessment?

At week 52 assessment patients' psychopathology remained significantly improved compared to baseline (t=4.42, df=14, p=.003). There was a strong trend towards sustained improvement in patients' attitude towards treatment (t=-2.43, df=14, p=.052). The improvement in the composite measure of compliance was not maintained.

5.11.7 What was the effect of being in the control group over the waiting period (baseline to week 26)?

In the control group, significant improvements in patients' psychopathology (PANSS-total; t=2.57, df=18, p<.001) over the waiting period were found. No significant changes in any of the other measures were observed.

5.11.8 What was the effect of training in the control group (week 26 to week 52 assessments)?

Following training in the control group (after the week 26 assessments) significant improvements were observed in psychopathology (PANSS-total; $t=5.67$, $df=11$, $p<.001$) and in patients' attitudes towards treatment (DAI-30; $t=-2.74$, $df=12$, $p=.019$). But not in any other measures or sub-scales.

5.11.9 Did training have any effect on service utilisation?

Service utilisation was analysed using Mann-Whitney U test because data were not normally distributed. There was no significant difference between the experimental and control group in the number of days CPNs' patients spent in hospital during the first and second 26-week phase of the trial (7.5 vs. 13.1 days and 13.3 vs. 11.0 days respectively).

5.12 CATEGORICAL CHANGE

The primary determinant of improvement was the proportion of CPNs whose patients showed a mean 10% or more reduction in total PANSS scores at the week 26 assessment. Table 5.13 shows the proportion of CPNs whose patients responded to training by group.

Table 5.13 CPNs whose patients responded to training by group (complete cases)

			Difference between groups (df=1)	
	Experimental	Control	χ^2	P
Baseline	0/27 (0%)	0/25 (0%)	-	-
Week 26	11/23 (48%)	5/19 (26%)	4.4	.035
Week 52	11/15 (73%)	10/14 (71%)	1.0*	ns

* Fishers exact test

5.12.1 Was there a difference between the experimental and control groups at the week 26 assessment?

At week 26 assessment 11 CPNs (48%) in the experimental and 5 CPNs (26%) in the control group (who had not yet been trained) showed a response. This difference between the two groups was significant (p=.035) suggesting that training had been effective. A greater than 20% reduction in PANSS scores was found in the patients of 6 CPNs (26%) in the experimental and 1 (5%) in the control group, this difference was not significant.

5.12.2 What was the effect of training in the experimental group (baseline to week 26)?

The McNemar test showed that, in the experimental group, the number of CPNs whose patients met the criteria for improvement in the PANSS was significantly increased at the week 26 ($p=.001$) assessment.

5.12.3 Was the effect of training sustained in the experimental group at the week 52 assessment?

At the week 52 assessment patients of eleven (73%) of the CPNs met the criteria for improvement. The same number as at the week 26 assessment. The McNemar test showed that there was a significant increase in the number of training responders ($p=.034$) from baseline assessment. Seven (47%) of the responders showed a greater than 20% improvement, from baseline, in total PANSS scores at the week 52 assessment.

5.12.4 What was the effect of being in the control group over the waiting period (baseline to week 26)?

The patients of five CPNs in the control group met the criteria for improvement at the week 26 assessment. This was a significant increase from baseline ($p=.031$).

5.12.5 Was the change in PANSS scores similar in training responders in the experimental and control groups at the week 26 assessment?

Patients of CPNs in the experimental group who were classified as training responders had a mean PANSS score of 77.1 at baseline and 57.2 at the week 26 assessment, an

improvement of 26%. In the control group, CPNs' patients who had responded had a baseline score of 66.9 and a week 26 score of 53, a improvment of 20%.

5.12.6 What was the effect of training in the control group (week 26 to week 52 assessments)?

At the week 52 assessment five additional CPNs (71%) in the control group showed improvements in the patients they were treating. This was double the number who improved at the week 26 assessment. Of the CPNs who were classified as responders at week 52, five (36%) showed a greater than 20% improvement in the psychopathology of patients they were treating.

5.12.7 Does the inclusion of trial drop-outs effect the impact of training?

The analysis was repeated to include trial drop-outs and missed assessments, who were rated as unimproved (table 5.14). The proportion of CPNs in the experimental group whose patients responded remained significantly greater than the proportion in the control group at week 26. There was no significant difference between the two groups at the week 52 assessment.

Table 5.14. Proportion of CPNs who responded to training by group (all cases)

			Difference between groups (df=1)	
	Experimental	Control	χ^2	p
Baseline	0 (0%)	0 (0%)	-	-
Week 26	11 (41%)	5 (20%)	5.63	.018
Week 52	11 (41%)	10 (50%)	3.29	ns

ns = not significant

5.13 DID TRAINING PREVENT RELAPSE?

The measure of relapse was defined as a mean 10% or more increase in total PANSS scores. None of the patients in either the experimental or control group met the criteria for relapse at either the week 26 or week 52 assessment. There were no patient suicides or deaths during the trial.

5.14 CLINICALLY SIGNIFICANT CHANGES

The clinical significance of change on the primary outcome measure was determined using Jacobson and Traux's (1991) criteria that a patient's post treatment and follow-up score extends to two standard deviations beyond the baseline mean score.

5.14.1 PANSS (table 5.15)

There was no significant improvement in the proportion of CPNs in both the experimental and control groups who showed a clinically significant change in the

patients they were treating (a mean reduction in total PANSS scores of 25.2 or more) at the week 26 and week 52 assessment. There were no significant differences between the two groups.

Table 5.15 Number (%) of CPNs showing clinically significant change by group on primary outcome measure (PANSS)

			Difference between groups (df=1)	
	Experimental	Control	χ^2	p
Baseline	0/27 (0%)	0/25 (0%)	-	-
Week 26	5/23 (22%)	3/19 (16%)	1.32	ns
Week 52	2/15 (13%)	2/14 (14%)	1.33	ns

ns = not significant

5.14.2 Attitudes towards treatment (table 5.16)

There was a significant proportion of CPNs in the experimental group whose patients showed a clinically meaningful improvement in attitudes towards treatment (a mean increase in scores of 20.4) at week 26 (p=.039) but not week 52 assessments. The proportion of CPNs in the control group whose patients showed meaningful improvements was not significant at the 26 week assessment but was, following training, at week 52 (p=.031).

Significantly more CPNs in the experimental group showed clinically meaningful improvements in patients attitudes towards treatment at the week 26 assessment. When the proportions were adjusted to include drop-outs and non-completers (rated as unimproved) 44% in the experimental group and 12% in the control group showed clinically meaningful improvments in attitudes towards treatment, a difference that was not significant.

Table 5.16. Number (%) of CPNs whose patients showed clinically significant change in attitudes towards treatment (DAI-30) by group

			Difference between groups (df=1)	
	Experimental	Control	χ^2	p
Baseline	0/27 (0%)	0/25 (0%)	-	-
Week 26	12/23 (52%)	3/19 (16%)	4.3	.038
Week 52	5/15 (33%)	7/14 (50%)	.45	ns

ns = not significant

5.14.3 Clinician rating of compliance (table 5.17)

There was a significant proportion of CPNs in the experimental group whose patients showed a clinically meaningful improvement in compliance (an increase in scores of 2.2) at week 26 (p=.021) but not week 52 assessments. The proportion of CPNs in the control group whose patients showed meaningful improvements was not significant at the week 26 but was, following training, at week 52 assessment (p<.019).

Significantly more CPNs in the experimental compared to the control group showed a clinically meaningful improvement in patient compliance at the week 26 assessment. When proportions were adjusted to include drop-outs and non-completers (rated as unimproved) 33% in the experimental, and 0% in the control group showed clinically meaningful improvements in compliance, a difference that was statistically significant ($p<.001$).

Table 5.17. Number (%) of CPNs showing clinically significant change in patient compliance, by group

			Difference between groups (df=1)	
	Experimental	Control	χ^2	p
Baseline	0/27 (0%)	0/25 (0%)	-	-
Week 26	9/23 (39%)	0/19 (0%)	8.1	.004
Week 52	5/15 (33%)	7/14 (50%)	.55	ns

ns = not significant

5.15 PREDICTION OF OUTCOME: LINEAR REGRESSION

Exploratory stepwise linear regression was used to identify factors predictive of clinical outcome (as measured using the PANSS-total score). Week 52 PANSS-total score was the dependent variable. Baseline scores were entered first and the variables under investigation were entered on the second level using stepwise procedures. Baseline scores

alone explained 35% of the variance in PANSS-total scores at week 52 assessment (R^2=.35, F=7.50, p<.001).

5.15.1 Predicting outcome from trainee demographics

The following trainee variables were entered into the exploratory stepwise regression: clinical experience, caseload size, age and attendance. No significant predictors emerged.

5.15.2 Predicting outcome from trainees' knowledge about medication management and clinical skills

The number of errors trainees made in rating the PANSS video, and their post-training scores on the Knowledge about Medication Management Questionnaire and the Cognitive Therapy Scale were entered into the exploratory stepwise regression. No significant predictors emerged.

5.15.3 Predicting outcome from patient characteristics

The following patient demographic and clinical characteristics were entered into an exploratory stepwise regression: age, age at onset of illness, duration of illness, number of inpatient admissions, and time since last admission. The final model incorporating number of inpatient admissions, age and duration of illness was predictive of PANSS-total scores at the week 52 assessment (R^2=.66, F=9.53, p<.001), and accounted for an additional 31% of the variance.

5.15.4 Predicting outcome from secondary outcome measures

Patients' baseline scores on the secondary outcome measures were entered into an exploratory stepwise regression. No significant predictors emerged. Scores at week 52 were also explored and, again, no significant predictors emerged.

5.16 PREDICTION OF OUTCOME: TRAINING RESPONDERS AND NON-RESPONDERS

Differences between patient and trainee demographic and clinical characteristics were explored in training responders and non-responders using the independent sample t-test. At the week 52 assessment 21 out of 29 CPNs had responded to training (a 10% reduction in total PANSS scores). Differences and associations in responder and non-responder demographic and clinical characteristics were compared using the paired sample t-test and the chi-square test.

5.16.1 Differences in CPN demographic and clinical characteristics

There were no significant differences between responders and non-responders on the following demographic characteristics: gender, ethnicity, age, years of experience, or academic qualifications. However, training responders were significantly more likely to be employed at a higher grade ($p<.032$).

5.16.2 Differences in CPN clinical skills and knowledge

Training responders were likely to be more clinically skilled than non-responders. The mean score on the CTS for trainees whose patients had responded to training was 33.0

(s.d. 6.9) compared with 28.7 (s.d. 4.6) for trainees whose patients did not respond (p=.038). There was no difference in the number of errors made by trainees in rating patients' psychopathology and clinical outcome.

There was no significant difference in the scores on the Knowledge about Medication Management Questionnaire in trainees whose patients did (mean 13.1, s.d. 2.2) and did not (mean 11.8, s.d. 2.7) respond to training.

5.16.3 Differences in patient demographic and clinical characteristics

Patients who had responded to training were likely to be younger in age than non-responders. Responders had a mean age of 36.5 (s.d. 8.2) years, compared with a mean age of 44.2 (s.d. 12.2) years in non-responders (p=.038).

There were no significant differences in the remaining personal or clinical characteristics of gender, ethnicity, age of onset, number of previous psychiatric admissions, diagnosis, smoking behaviour, alcohol consumption, registration on the care programme approach or previous detention in hospital under the mental health act.

5.16.4 Differences in secondary outcome measures

No significant differences were found in the baseline scores of responders and non-responders on any of the secondary outcome measures, or their sub-scales.

5.16.4.1 Are training responders more compliant?

At the week 52 assessment, training responders had significantly lower scores on the DAI-30 (7.9 vs. 21; t=2.42, df=28, p=<.001), indicating a more positive attitude towards treatment, and a higher clinician rating of compliance (6.2 vs. 4.6; t=2.12, df=26, p=<.001), indicating more consistent adherence to treatment.

5.16.4.2 Differences in other secondary outcome measures

None of the scores, at week 52, for the secondary outcome measures were significantly different between training responders and non-responders.

CHAPTER 6: DISCUSSION

6.1 MAIN INVESTIGATION

The primary aim of this trial was to demonstrate the efficacy of medication management training for CPNs working with patients with schizophrenia taking antipsychotic medication.

A number of studies have demonstrated that medication management interventions such as compliance therapy (Kemp *et al.*, 1996; 1998), behavioural tailoring (Boczkowski *et al.*, 1985) and patient education (Macpherson *et al.*, 1996a; Gray, 2000) are effective in improving compliance and the understanding of treatment in people with schizophrenia. Many of these studies have focused on compliance as the primary outcome of interest. However as Haynes *et al.* (1999) argue, improving adherence *per se* may not benefit the patient unless it is accompanied with improvements in clinical outcome. There have been no trials that have established that clinicians in routine practice can be trained to produce similar outcomes to those found in clinical trials.

The primary aim of this trial was, therefore, to test the hypothesis that compared to standard care, the application of a medication management intervention delivered by CPNs, post-training, would lead to significant improvements in the psychopathology of the patients they were treating. The secondary aims were to test the hypotheses that training would lead to significant improvements in patients' compliance with antipsychotic medication, insight into their illness, antipsychotic side effects, and service utilization.

Two other issues were of interest. Firstly, the literature suggests that psychotropic medication in the United Kingdom is generally poorly prescribed (Newton *et al.,* 1996) and guidelines which promote good practice (such as the Maudsley Prescribing Guidelines; Taylor *et al.*, 1999) are largely ignored by prescribers. The effect on prescribing of training CPNs in the use of evidence based guidelines has not been explored. Secondly, although previous studies have shown that training can lead to improvements in patient outcomes (Brooker *et al.*, 1992a; Brooker *et al.*, 1994; Lancashire *et al.*, under review) the link between the clinicians' level of skill and the patients' clinical outcome have not been established. This study therefore also explored this relationship.

In order to test the primary hypothesis, sixty CPNs were randomly assigned to either an experimental or waiting list control group. Each CPN identified two patients on their caseload who had been (within the previous 12 months), or were currently, non-compliant with their antipsychotic medication. A research worker blind to the training condition assessed these patients at baseline and at week 26 and week 52 follow-up. CPNs in the experimental group received 80 hours of training immediately following the baseline assessment. CPNs in the control group continued with their routine care and then received training following the week 26 assessment. The primary outcome measure was the Positive and Negative Syndrome Scale (PANSS), a valid and reliable measure of patients' psychopathology. The mean of the two patients' scores for each outcome measure was used for the analysis. Response rate and clinical significance of change was

analysed in addition to mean scores. As the data were normally distributed within and between group analyses were made using parametric statistics. Patient and CPN drop-out were managed using the intention to treat principle with the last known observation carried forward.

6.2.1 Were CPNs and patients representative?

The CPNs were drawn from two large mental health Trusts in the South of England. Very few of the CPNs who initially agreed to participate dropped out of the trial prior to receiving training. Their demographic characteristics are broadly consistent with the 1997 survey of CPN practice in England and Wales (Brooker and White, 1998). The proportion of female CPNs is similar (56% of CPNs were female in this trial compared with 57% in the National survey), as was the CPNs age (39 vs. 39 years). The majority of CPNs (59%) in this trial and the National survey (61%) were employed at nursing grade 'G'. The mean length of CPNs' clinical experience in this study was slightly shorter (7.9 vs. 14 years). As expected, given the geographical location of the trial, CPNs in this study were from a more diverse ethnic background: 66% of CPNs were from a non-white ethnic background compared to 10% in the National survey. Compared to the national average, a higher proportion of CPNs had attained at least a diploma level academic qualification, again this would be predicted given the increased availability of training in the geographical area where the trial was conducted (Gournay and Brooker, under review). The number of patients on CPNs' caseloads was marginally higher in the national survey (38.3 vs. 35.3).

CPNs were randomised into geographical clusters to control for the possibility of contamination. This method increased the risk that the two groups may have different characteristics. However, the experimental and control groups were well balanced on most demographic variables (with the exception of years of experience) and baseline knowledge scores. The control group had slightly higher baseline scores on the Cognitive Therapy Scale.

Patients in this trial were representative of patients currently in receipt of services in the UK. The demographic and illness profiles of patients were similar to that seen in UK trials of training interventions for CPNs (Brooker *et al.* 1994), patient education (Macpherson *et al.*, 1996a), and compliance therapy (Kemp *et al.* 1996; 1998). Mean age in the present study (40.4 years) was within the range reported in the trials cited (35.5-45.2 years). A little over half of the patients in all of the studies were male and approximately two-thirds of patients were of non-white ethnic origin.

Duration of illness in the other studies ranged from 9.6 years (Kemp *et al.* 1998) to 23.4 years (Macpherson *et al.* 1996a). The duration of illness in this trial (13.08 years) was towards the lower end of this range. The number of previous psychiatric admissions was three, lower than the number reported in the earlier studies (4.3, Kemp *et al.*, 1998; 6.4, Macpherson *et al.* 1996a). The majority of patients in previous studies had schizophrenia (58.2%, Kemp *et al.* 1998; 100%, Macpherson *et al.* 1996a). The proportion of patients in this trial with a diagnosis of schizophrenia was within this range (85%).

Because outcome measures vary across studies it is difficult to make meaningful comparisons in terms of patients' psychopathology. In this and previous trials, patients were moderately symptomatic. Patients in the Compliance Therapy study (Kemp *et al.*, 1998), however, were more symptomatic and were more likely to be under a section of the Mental Health Act. This is because the trial was conducted in an inpatient, as opposed to a community, setting with patients in an acute phase of their illness. Baseline scores on the Drug Attitude Inventory, Expanded Schedule for the Assessment of Insight and clinician rating of compliance were similar to the Kemp *et al.* (1998) trial. Randomisation achieved groups that were well balanced on demographic and clinical variables and pre-treatment scores.

The only substantial difference between the two groups was the training that the nurses received. It is likely therefore, that any differences between the groups can be attributed to the training intervention itself rather than to non-specific factors.

6.1.2 Trainee hypothesis: medication management training will enhance CPNs' clinical skills and knowledge

The hypothesis that medication management training will enhance CPNs' clinical skills and knowledge was tested by: 1. Examining within group changes using the paired samples t-test; 2. Comparing the proportion of CPNs who were rated as having satisfactory cognitive and compliance therapy skills (a score of 30 or more on the CTS) pre- and post-training; and 3. Determining the proportion of trainees who were able to rate a patient's mental state to a satisfactory standard.

The hypothesis that medication management training would enhance CPNs' clinical skills and knowledge were supported by the data.

Significant improvements in mean scores on both the Cognitive Therapy Scale and the Knowledge about Medication Management Questionnaire were observed post-training. The degree of improvement was similar in both the experimental and waiting list control groups suggesting that the quality and standard of training were consistent over time. Significantly more trainees were able to demonstrate satisfactory clinical skills, post training, and over half of CPNs demonstrated that they were able to rate a video of a patient being interviewed to an adequate standard.

The results are consistent with those reported in the pilot study (chapter 3) and suggest that training is effective in enhancing CPNs' medication management skills.

6.1.3 Primary hypothesis: Medication management training will be superior to standard care in improving patients' psychopathology

The hypothesis that medication management training will be superior to standard care in improving patients' psychopathology was tested by using the ANCOVA to determine mean response over time and comparing the proportion of patients in each group who responded to training (a mean reduction in psychopathology of 10%).

The hypothesis that medication management training would be superior to standard care in improving patients' psychopathology (measured using the PANSS) was supported by the data.

A comparison of mean scores at week 26 showed a 21% reduction in PANSS-total scores in the experimental group compared with a 10% reduction in the control group. The proportion of CPNs in each group whose patients responded to training also supported the primary hypothesis. At the week 26 assessment the patients of 48% of CPNs in the experimental group and 26% in the control group responded to training. The improvements were not, however, clinically significant using Jacobson and Traux's (1991) stringent criteria.

Within group analyses (of mean scores and response to training) also support the primary hypothesis. When CPNs in the control group received training following the week 26 assessment a similar (15%) improvement in psychopathology was found over the duration of the trial.

Improvements in psychopathology, the trials' primary aim, suggest that compliance with antipsychotic medication has been enhanced. The improvements in compliance and reduction in psychopathology may be because training has been effective and CPNs are applying in clinical practice the new skills they have acquired. However, there are three alternative explanations for the improvements in psychopathology. Firstly, that training raised CPNs' awareness of the risk of relapse following non-compliance with

antipsychotic medication and trainees have therefore paid more attention to ensuring that patients are taking their medication. Secondly, it is possible that training resulted in CPNs spending more time with patients and this increased contact improved psychopathology. Finally, CPNs may have had a substantial influence on the way in which psychotropic medication is prescribed.

6.1.4 Secondary hypotheses

6.1.4.1 Medication management training will be superior to standard care in improving patients' compliance with antipsychotic medication?

The hypothesis that medication management training would be superior to standard care in improving compliance with antipsychotic medication was supported by the data.

The ANCOVA showed that, at the week 26 assessment, medication management training was superior to standard care in enhancing patients' attitudes towards treatment and compliance. At the week 52 assessment improvements in patients' attitudes towards treatment were maintained. Finally improvements in attitudes towards treatment and compliance were shown to be clinically meaningful.

These findings support the conclusion that the improvements in psychopathology are as a result of enhanced compliance with medication. They may also suggest that improvements in patients' attitudes towards treatment are as a results of enhanced clinical practice in CPNs who have received training. Indeed, training responders had lower scores on the DAI-30 at the week 26 assessment and higher post-training scores on the

CTS. However, exploratory stepwise regression did not support this conclusion. Scores on the DAI-30 and clinician rating of compliance did not predict improvements in psychopathology.

6.1.4.2 Medication management training will be superior to standard care in improving patients' insight into their illness?

The hypothesis that medication management training would be superior to standard care in improving patients' insight into their illness was not supported by the data.

There were no significant differences in scores within or between the groups on the Expanded Schedule for the Assessment of Insight at week 26 or 52 assessments.

The absence of any effect on insight is surprising, given the improvements in insight noted in two earlier trials (Macpherson *et al.*, 1996a; Kemp *et al.*, 1996; 1998) and is inconsistent with the conclusion that improvements in patients' psychopathology can be explained by CPNs' enhanced clinical practice. However, the emphasis of the training was on examining and testing patients' beliefs about medication and focusing on the use of pharmacological treatments to manage specific symptoms or problems rather than enhancing insight, for example, by helping patients to relabel symptoms as part of an illness. An alternative explanation may be that patients already had a moderately good level of insight that was unlikely to improve. Baseline scores on the SAI(E) were slightly higher that those reported, pre-training, in the compliance therapy trial (43.2% vs. 37.6%

(Kemp *et al.*, 1998)). Suggesting that there was less room for improvement in a stable group of patients living in the community.

6.1.4.3 Medication management training will be superior to standard care in preventing relapse?

The hypothesis that medication management training would be superior to standard care in preventing relapse was not supported by the data.

Very few patients in either group experienced a relapse of their illness during the trial. There were no significant differences between the experimental and control groups in the proportion patients who relapsed (>10% increase in scores of the PANSS). In fact only one patient in the control group experienced a relapse by the week 26 assessment. Inpatient bed days were relatively low in both groups. There was no significant difference in the number of inpatient bed days CPNs' patients used at either the week 26 or week 52 assessments.

The absence of any effect on relapse rates and inpatient bed days is surprising given the differences in improvements in psychopathology and compliance observed between the two groups. However, the findings are consistent with the results from the compliance therapy study (Kemp *et al.*, 1998) which also reported no significant differences, at 18 months, in the overall time patients spent in hospital. It is possible that, because the majority of patients were treated using long acting depot antipsychotic preparations, it would take at least six months (Walburn *et al.*, under review) for a relapse to occur and

that the re-emergence of symptoms would be progressive rather than abrupt. Thus, making it too difficult to detect differences in relapse rates between the two groups. For the anticipated differences to be observed, a substantially longer follow-up period would be required without the confounding effect of a delayed training intervention in the control group.

6.1.4.4 Medication management training will be superior to standard care in improving the prescribing of antipsychotic medication?

The hypothesis that medication management training would be superior to standard care in improving the prescribing of antipsychotic medication was not supported by the data.

There were no changes in the mean dose of antipsychotic medication prescribed in either group at the week 26 or week 52 assessments. The stability of patients' psychotropic medication in this trial suggests that the improvements in patients' psychopathology can not be attributed to changes in treatment regimes. This lends further weight to the conclusion that improvements in psychopathology are as a result of improved compliance. However, the absence of any impact of training on the prescribing of antipsychotic medication is surprising. At the baseline assessment the quality of psychotropic prescribing was poor. Mean doses of antipsychotic medications were high, there was a high proportion of patients (25%) on more than one antipsychotic, 49% of patient were on long term anticholinergic medication, and very few patients were on clozapine. It is widely assumed, although there are no data to support the idea, that CPNs influence what and how psychiatrists choose to prescribe. A substantial component of the

medication management training was therefore focused on psychopharmacology and the use of evidence based guidelines as a basis for making treatment decisions. Training appears to have had no effect on prescribing patterns and throughout the trial the mean dose (in chlorpromazine equivalents) was stable. An explanation for the lack of improvement in prescribing may be a perception among clinicians that, despite some evidence to the contrary (Desai *et al.,* 1999), changing or altering medication may risk or precipitate a relapse. Such prescribing practices are undesirable if unwanted antipsychotic side effects are to be managed and the longer term risk of tardive dyskinesia is to be minimised (Gray 1998a). To maximise the effect of training it would require genuine multidisciplinary collaboration concerning prescribing decisions.

6.1.4.5 Medication management training will be superior to standard care in improving side effects from antipsychotic medication?

The hypothesis that medication management training would be superior to standard care in improving side effects from antipsychotic medication was not supported by the data.

The ANCOVA showed no significant differences between groups in the LUNSERS total score at the week 26 assessment. There was little change in total scores over time in each group, a finding that is inconsistent with the conclusion that training led to enhanced compliance with antipsychotic medication (side effects should get worse if patients are more compliant). This lack of change may be because the LUNSERS is not sufficiently sensitive to change over time.

No differences were observed between the groups over time on any of the LUNSERS sub-scales; anticholinergic, psychic, hormonal and miscellaneous side effects and allergic reactions. However, there was a trend towards a reduction in EPS and red herrings. This may indicate that training resulted in more appropriate use, by patients, of anticholinergic medication to manage EPS.

Mean LUNSERS total scores at baseline suggest that patients were experiencing a moderate level of side effects. The failure of training to improve the management of these symptoms can most obviously be explained by the stability in psychotropic prescribing. However, a range of non-pharmacological strategies (e.g. exercise and calorie restriction to treat weight gain) for managing side effects were taught during the course. The failure to detect any effect from these interventions requires alternative explanations. It is possible that CPNs did not use the interventions. However, this is by no means certain. Because the LUNSERS is a self-report measure of perceived side effects, training may have made patients aware of symptoms that they did not know about or had not previously attributed to their illness. This would increase LUNSERS scores and would effectively cancel out any positive effect of training. The trend towards significant differences in scores between the groups over time on the red herring sub-scale of the LUNSERS lends support to this conclusion. Alternatively, side effects may still have been rated by patients as being present even if trainees had been successful in teaching them new coping strategies (e.g. a high fibre diet to treat constipation).

6.2 TREATMENT OUTCOME FOR SKILLED AND UNSKILLED CPNs

Following training 14 (61%) CPNs in the experimental and 16 (55%) in the control group were rated as having satisfactory clinical skills. If training had changed practice, CPNs' knowledge and clinical skills should be predictive of clinical outcome. This was not the case. Exploratory stepwise linear regression did not suggest that these factors were important in determining response. However, trainees in the experimental group whose patients responded were significantly more skilled than CPNs whose patients did not respond. These inconclusive findings cast some doubt on the conclusion that improvements in patients' psychopathology are as a result of enhanced clinical practice by CPNs who had received training. The trial was not powered to explain which factors predict response. Previous studies evaluating training have similarly not reported any link between clinical skills and patient outcomes (Brooker *et al.*, 1992a; Brooker *et al.*, 1994; Lancashire *et al.*, under review). Larger trials will be needed to address this important question.

The interplay between training, clinical practice, and patient outcomes is clearly very complex and this trial may simply not have had enough statistical power to detect any relationships that exist. This is, however, by no means certain. An alternative explanation may be that training raised CPNs' awareness of compliance with antipsychotic medication. This may mean that compliance improved because CPNs paid more attention to whether or not patients were taking medication but did not apply the specific cognitive behavioural skills they had acquired during training.

6.3 DURABILITY OF IMPROVEMENTS IN THE EXPERIMENTAL GROUP AT THE WEEK 52 ASSESSMENT

In the experimental group, within group analyses of mean scores showed that improvements in psychopathology were maintained at the week 52 assessment but did not continue to improve. This may suggest that CPNs continued to implement training and maintain compliance in the patients they were treating. However, in the compliance therapy trial (Kemp *et al.*, 1998), patients' psychopathology, attitudes towards treatment, compliance and insight were all stable between the six and twelve month follow-up assessments despite receiving no additional intervention. An alternative explanation may be that CPNs' practice was enhanced during and immediately following training but did not continue for the duration of the trial. If this were the case degradation in psychopathology would be predicted over time (i.e. the next three to four years). Exploring this hypothesis is, however, beyond the scope of this trial.

6.4 OVERALL VALUE OF MEDICATION MANAGEMENT TRAINING

Although medication management training was superior to standard care in this trial, the impact of training should not be overestimated. Although 48% of patients responded to training there was no effect on patients' insight or side effects. Although patients generally had a more positive attitude towards treatment, some ambivalence persisted. This suggests that the risk of non-compliance and relapse in the future remains high.

6.5 STABILITY OF THE CONTROL GROUP

Compliance has been observed to improve under scrutiny (Blackwell, 1996). There was a significant improvement in patients' psychopathology in the control group prior to those CPNs receiving training. A minority of patients (26%) responded to standard CPN treatment and only one patient experienced a relapse of their illness. These results seem to suggest that the process of CPNs being recruited to the trial and facilitating patient interviews had a therapeutic effect. This phenomenon has been observed in other studies (Wykes *et al.*, 1999). Alternatively, CPNs' practice may improve under scrutiny. Being involved in a trial may make CPNs think about their practice and re-evaluate the care they provide.

6.6 PATIENT VARIABLES ASSOCIATED WITH A GOOD OUTCOME

Variability of response to training is expected in patients with psychosis. In this trial patients' age, duration of illness, and number of previous psychiatric admissions were predicative of a better outcome. Although these finding have not been reported in previous trials of compliance interventions, this may suggest that compliance interventions will be more efficient if they are targeted at patients with less chronic or enduring symptoms where the course of their illness may be diverted.

6.7 COMPARISON WITH OTHER TRIALS

This is the first trial that has evaluated the impact of medication management training on patient outcomes. As such there are no studies against which this trial can be directly

compared. However, it is important to place this trial in the context of controlled trials of compliance interventions (Boczkowski *et al.*, 1985; Macpherson *et al.*, 1996a; Kemp *et al.*, 1998) and controlled and uncontrolled trials of CPN training (Brooker *et al.*, 1992a; Brooker *et al.*, 1994; Lancashire *et al.*, under review).

6.7.1 Comparison with other controlled trials of compliance interventions

As has already been discussed, the demographic and clinical characteristics of patients in this trial are broadly comparable to other trials of compliance interventions (Boczkowski *et al.*, 1985; Macpherson *et al.*, 1996a; Kemp *et al.*, 1998). The rates of trial drop-out and trial refusal in this study are lower than that found in the compliance therapy study (Kemp *et al.*, 1998).

Outcome measures vary across studies making it difficult to make meaningful comparisons. For the purposes of discussion, the percentage changes in psychopathology and attitudes towards treatment (probably the most valid and reliable measure of compliance) from pre-training to final follow-up are shown in table 6.1 (where data are available).

Table 6.1 British controlled trials of interventions to enhance compliance in patients with psychosis: mean score at pre-training and final follow-up, and percentage change (raw data could not be extracted from one trial)

	Pre	18mfu	% change	Pre	18mfu	% change
Kemp *et al.* 1998	7-item BPRS			DAI-30[1]		
Compliance therapy	20.3	12.5	38%	45.3	50.9	8.6%
Controls	19.2	14.8	23%	44.1	48.2	4.1%
			% change			% change
Hayward *et al.* 1995	BPRS			AMQ[2]		
Medication self manage.	Data not reported		-6.1%	Data not reported		22.8%
Controls			-5.1%			8.3%
	Pre	Wk 26	% change	Pre	Wk 26	% change
Current trial	PANSS			DAI-30[3]		
Experimental	72.5	57.6	21%	0.4	9.0	28%
Controls	66.5	60.2	9%	2.7	6.6	12%

[1]Results expressed as a percentage of complete compliance

[2]Attitudes towards medication questionnaire

[3]Raw score (-30 to +30 scale)

In contrast to the findings of this trial, none of the previous studies demonstrated any significant effect on patients' psychopathology at the final follow up assessment. This is surprising given the improvements in compliance that were found, especially in the compliance therapy trial (Kemp *et al.,* 1998). However, both studies were conducted in an inpatient environment where psychopathology should have improved anyway effectively swamping any experimental effect. Improvements in attitudes were similar to Hayward *et al.* (1995) and greater than Kemp *et al.* (1998). In the control group improvements were slightly greater (12%) than previous studies (Kemp *et al.*, 1998 and Hayward *et al.*, 1995).

Improvements in patients' insight were found in the trials by Kemp *et al.* (1998), who observed a 31% improvement in insight and Macpherson *et al.* (1996a) who observed a more modest improvement in insight. Hayward *et al.* (1995) and the current trial failed to show any significant change in patients' insight. Changes in insight in the control groups range from a 1% reduction in the present trial, to a 20% increase in the compliance therapy trial (Kemp *et al.*, 1998).

6.7.2 Explanations for difference in outcome – controlled trials of compliance interventions

Some explanations for the conflicting results found by Hayward *et al.,* (1995) and Macpherson *et al.* (1996a) are advanced in chapter one.

The two trials (Hayward *et al.*, 1995; Macpherson *et al.*, 1996a) which reported no significant impact on compliance were both brief interventions (respectively, 3 half hour sessions and 1 to 3 sessions). In the compliance therapy trial, which found improvements in compliance, patients received 4-6 sessions with an average of 3-3.5 hours face-to-face contact, double that in the previous studies. It was anticipated, although not quantified, that CPNs in this trial would have approximately 20 formal sessions with patients discussing medication. Additionally, they would, as part of their work as a CPN, spend a substantive amount of informal and unstructured time with patients discussing all aspects of their treatment and care. Given the nature of psychotic illnesses such as schizophrenia it is perhaps not surprising that interventions of a longer duration produce better outcomes. There are a number of potential benefits of longer treatment. Firstly, there is an opportunity for "over-learning" by repeating interventions to derive maximum benefit. Secondly, there are opportunities for patients to learn by experience the effects of changing or stopping medication. Longer treatment will also allow therapists to follow through plans for addressing problems with medication making amendments and changes with the patient as necessary. Similarly, patients may set long-term goals (such as getting a job) that they want to achieve. A longer intervention will allow the therapist to follow through, with the patient, any plan that had been worked out.

The effect of training on compliance in this trial is more substantial than in the study by Kemp *et al.* (1998). This would be predicted given the difference in the amount of both structured and unstructured face-to-face contact between patients and therapists (10-20 hours in the present trial vs. 3-3.5 hours in the compliance therapy trial). One explanation

may be that training has produced CPNs who are as skilled as the "expert" therapists in the compliance therapy trial. They produce better results because they have more contact with patients. There is, however, little evidence from the trial to support this conclusion. An alternative explanation may be that more contact time with a less skilled therapist is more effective than a few sessions with a highly skilled, trained (and expensive) research psychiatrist.

Shared characteristics in the interventions used may explain the similarity of outcome between this trial and the compliance therapy study (Kemp *et al.*, 1998). In both studies the focus of the intervention was on working collaboratively with patients, exploring ambivalence towards taking medication. Confrontation, lecturing and debating with patients about medication was similarly avoided in both studies.

The differences in approaches may also explain the inconsistencies in results that were observed with the patient education trial (Macpherson *et al.*, 1996a). In the patient education study the emphasis of the intervention was on providing individually tailored information, this led to improved knowledge but not compliance. Although patient education does not appear to be effective in enhancing compliance, providing information is an important component of good medication management because patients with psychotic illnesses generally have such a poor understanding of their treatment (Macpherson *et al.*, 1996a; Gray *et al.*, 1995). Within both compliance therapy (Kemp *et al.*, 1997) and medication management training, the importance of providing patients with information about their illness and treatment is emphasised. However, neither study

attempted to measure the impact of the intervention on patients' knowledge. Future trials should consider knowledge to be an important outcome to measure.

The three previous studies of interventions to enhance compliance failed to show any impact on patients' psychopathology. As discussed in chapter one improving compliance without improving clinical outcomes does not benefit the patient. However, in this trial improvements in psychopathology were found and appear to be as a result of enhanced compliance with medication. Since the Macpherson *et al.* (1996a) study of patient education and the Hayward *et al.* (1995) study of medication self-management failed to show enhanced compliance, improvements in psychopathology would not be predicted. Kemp *et al.* (1998) did, however, show improvements in compliance and should therefore be able to demonstrate improvements in psychopathology. In this trial the PANSS, a very robust measure of patients' psychopathology, was used as the primary outcome measure. In the Kemp *et al.* (1998) trial, the 7-item version of the BPRS (Brief Psychiatric Rating Scale, Lukoff *et al.*, 1996) was used. It is possible that the BPRS was not sensitive enough to detect differences, primarily in positive symptoms between the two groups. This is especially likely to be true considering that the trial was conducted in an inpatient setting where actual compliance (as opposed to predicted future compliance that the DAI-30 measures) is likely to be extremely good.

6.7.3 Comparison with other training trials

There have been three previous studies, all non-randomised controlled trials which have evaluated the impact of training on clinical outcomes in patients with psychotic disorders

(Brooker *et al.*, 1992a; Brooker *et al.*, 1994; Lancashire *et al.*, under review). Brooker *et al.* (1992) and Brooker *et al.* (1994) were controlled trials of training CPNs in family interventions and Lancashire *et al.* (under review) was an uncontrolled trial of psychosocial interventions training (the Thorn programme). Although these studies had different designs, interventions and assessments, comparison of the impact of training on patients' psychopathology is useful (table 6.2). The percentage change is psychopathology could not be calculated for the Brooker *et al.* (1992) study.

Table 6.2 Studies of training interventions for CPNs that used changes in patients' psychopathology as the main outcome measure

Study	Pre	24mfu	% change
Brooker *et al.* (1994)	Measure of psychopathology: KGV		
Experimental	10	5	50%
Control	11	4	64%
	Pre	12 mfu	% change
Lancashire *et al.* (under review)	Measure of psychopathology: KGV		
Experimental group	15.9	11.1	30%
	Pre	12 mfu	% change
Current trial	Measure of psychopathology: PANSS		
Experimental	72.5	56.8	22%
Control	66.5	56.8	15%

All of the three training studies demonstrated significant improvements in patients' psychopathology, even though the skills that were taught and the period of study that trainees underwent, varied dramatically.

6.7.4 Explanations for difference in outcome – studies of training interventions for CPNs

Despite different training packages varying substantially in duration (8-40 days) and content (medication management, schizophrenia family work, Thorn training) all reviewed studies led to improvements in patients' psychopathology. It seems reasonable to propose that the longer the training, the more skilful the CPN and consequently the better the patients' clinical outcome. In theory Thorn training (Lancashire *et al.* under review) should, because CPNs are trained in a range of techniques for a substantially longer period of time, produce the best therapeutic outcomes. But in practice this does not appear to be the case. The improvements in psychopathology in the Lancashire *et al.* (under review) study and this trial were broadly similar. One explanation may be that as the research methodology becomes more robust the degree of improvements found reduces. The study that produced the largest improvements (Brooker *et al.*, 1994) is methodologically much weaker than Lancashire *et al.*, (under review) which in turn is methodologically weaker than the present trial, which found more modest improvements in psychopathology. The methodological merits of these trials are discussed in chapter one.

Alternatively, it is possible that patients only have a limited potential to make improvements in their psychopathology and there are no additive effects of using different therapeutic approaches. It is also possible that the three training interventions that have so far been tested had a similar placebo effect. Training, perhaps, engenders a

more optimistic therapeutic attitude in trainees but does not lead to the delivery of the intervention they have been trained to use. The results of the trial do seem to suggest that this hypothesis warrants further investigation.

Finally the shared characteristics in the training packages may explain the similarity of outcome. In all three studies, trainees were presented with a clear treatment rationale, and rehearsed skills using role-play. All involved assessing patients using valid and reliable assessment tools to produce a formulation. All involved the use of highly structured clinical supervision. A number of important new questions are raised by this trial and further research, for example controlling for training time, the attitudes and motivation of CPNs and sufficiently powered to detect a link between clinicians skills and patient outcome, is required.

6.8 IMPLICATIONS FOR TRAINING AND CLINICAL PRACTICE

In this trial, medication management training was acceptable to CPNs. Attendance at training was good, satisfaction was high and knowledge and clinical skills improved significantly. CPNs also appear to implement the knowledge and skills that they have acquired in clinical practice, with the majority producing clinically meaningfully improvements in their patients' psychopathology. Medication management training was not harmful, no patient suicides or deaths occurred during the study. Any intervention which attempts to raise patients' awareness of their illness may potentially increase the risk of suicide (Amador *et al.*, 1996).

The comparison of this trial with other controlled trials of interventions to enhance compliance broadly suggests that working collaboratively with patients in a structured way to explore ambivalence towards taking medication is the key to effective treatment. The duration of treatment may also affect outcome. In this trial, patients received around 20 sessions plus additional informal work from CPNs. Very brief interventions appear to be of little benefit.

This trial and the other studies evaluating clinical outcomes of training for CPNs suggest that training in the use of valid and reliable assessment tools, a manualised approach to treatment and the use of role-play to rehearse clinical skills are the key components of effective training for CPNs. The duration of training does not appear to affect outcome. In this trial CPNs received 80 hours of training delivered over ten days and produced similar improvements in patients' psychopathology than more substantive programmes. The medication management model (i.e. brief and focused) of training may be the preferential model for disseminating interventions in the NHS.

6.9 LIMITATIONS OF THE TRIALS

The major weakness in the trial design was the use of standard care as the control intervention. The lack of a credible (inert) control training condition of equal duration means that improvements in the experimental group could be attributed to the attention the CPNs received rather than the specifics of the intervention. The provision of training in the control group following the week 26 assessment also make it impossible to make between group comparisons at the week 52 assessments which would have allowed more

robust analyses of the durability of training. However, unlike a drug trial, the ethics of providing ineffective training to busy CPNs are dubious. It is likely that attendance to a control training intervention would be poor. Further, if CPNs in the control group were not offered training as an incentive to participate in the trial they would be unlikely to facilitate patient interviews. Hence the design was chosen for ethical and pragmatic reasons.

The use of highly experienced trainers and clinicians may weaken the argument that the training package was effective. Much emphasis was placed on preparing the training material in advance, delivering it in a structured format with a detailed treatment manual for CPNs to follow. However, it remains a possibility that the use of a small number of trainers, who had a vested interest in demonstrating the efficacy of training, may have been more effective than an independent trainer working independently of the research group. Although it seems unlikely that the motivation of the trainer can fully explain the outcomes of this trial it is a consideration for future research.

The decision to ask CPNs to identify patients to participate in the trial after they had been randomised was done for practical reasons. It enabled CPNs to organise study time once they knew which group they were in and allowed the maximum amount of time for patient interviews to be conducted. However, it is a potential source of bias as CPNs in the experimental group may have identified patients who were easier to work with. Patients in the experimental and control groups were, however, well balanced across a range of variables. Outcomes in both groups following training were also very similar.

Another methodological problem was the way in which compliance was measured. The problems in measuring compliance have been outlined in chapter one. The Drug Attitude Inventory and clinician rating are indirect proxy measure of patients' compliance. A more direct measure may have been preferable, although, all current available methods of measuring compliance with antipsychotic medication have substantial drawbacks. Pill counting has been used in a number of previous studies but is obviously open to abuse and is not suitable when a large proportion of patients are administered medication as a depot. Serum assays are expensive, invasive and are not available for the full range of antipsychotics (Kemp *et al.*, 1998). Urine tests for a drug or its metabolite may overestimate compliance in antipsychotics with a long half-life (Churchill, 1985) and may fail to detect low doses. Further, they only measure compliance within a few days and are of limited value in assessing partial compliance. More robust and accurate measures of adherence to treatment may need to be developed.

CPNs' knowledge and skills were measured at the beginning and end of training. It would have been preferable for CPN assessments to be performed at the same time as their patients. This would have allowed for a more robust comparison of the relationships between skills and knowledge acquisition and patient outcome. However, some of the assessments, specifically the video role-play, could not be administered in a clinical setting because a suitable environment was needed, as was an actor to role-play the patient.

The study would have been improved by having direct measures of the amount of time CPNs spent with their patients and the medication management interventions and skills they used. One method of doing this would be to ask CPNs to submit audiotapes of their sessions with patients. These tapes could then be independently rated. Brooker *et al.* (1992) and Lancashire *et al.* (under review) have attempted to use such methodology in the past with some success. The proportion of submitted interactions tends to be low, for example Brooker (1992b) reported that only a "minority" of tapes were submitted for analysis, many of which were either blank or unclear. Rating audiotapes is both time consuming and expensive (it takes approximately 3-5 hours to rate a single one hour tape). Further, if CPNs think that they are going to be evaluated in practice then they are likely to 'perform' well. However, once they are no longer under scrutiny then they would revert back to their normal level of practice. Understanding how trainees integrate skills into their practice is a major methodological challenge for future research.

This trial is the first randomised-controlled trial to examine the impact of CPN training on patients' clinical outcomes. Despite the limitations that have been discussed, this trial has several strengths. Randomisation was successful in achieving well balanced groups across many variables that were not contaminated by CPNs in the experimental and control groups working together. The study had sufficient power to detect a difference between groups. The drop-out and refusal rates were respectable and assessments were performed blind. Analysis was not restricted to mean scores but included categorical and clinically significant change. The conclusions that are drawn are therefore considerably more robust.

6.10 FUTURE RESEARCH

This trial represents a first attempt to evaluate the impact of CPN training using robust randomised controlled methodology. As such it should be considered to be an exploratory piece of work that will inform future definitive trials of both medication management and other training interventions for CPNs. Further multi-centre research is needed to determine the way in which training affects clinical outcomes. A controlled trial comparing medication management with an inactive (or other focused) training intervention would be useful in determining whether training gives CPNs new skills which they put into practice or inspires and motivates them to work more closely with their patients. Although this poses an ethical problem of providing CPNs with a training programme which is known to be ineffective, it is a dilemma that must be addressed. One option would be to compare medication management training with an alternative training intervention which has been shown to benefit CPNs but should have little impact on patients' compliance or psychopathology. An alternative training intervention may be in the detection and management of side effects or delivering an educational intervention, both of which would be beneficial to both CPNs and patients but should have minimal effect on compliance. Such a trial could be used to begin to identify which aspects of training are most effective in producing changes in specific aspects of psychopathology and consider the duration of training courses and level of post training supervision that is required.

Although medication management training appears helpful in patients with psychotic disorders, non-compliance is a major problem in patients with other psychiatric (such as depression) and physical (such a hypertension and diabetes) illnesses. A controlled trial comparing the impact of an adapted medication management training package for primary care or district nurses with standard care would be an important progression of this research.

6.11 WIDER IMPLICATIONS

This trial demonstrates that CPNs' medication management knowledge and skills can be enhanced with training and that this results in lower levels of psychopathology in the patients they are treating. Current care is fragmented with different professionals responsible for different facets of care. The psychiatrist prescribes medication, the CPN administers it and then monitors the patient for side effects and signs of relapse. CPN prescribing may be a logical progression from the medication management training described in this trial. Prescribing would allow the CPNs to respond quickly to untreated symptoms, side effects or relapse. Such practice should maximise patients' compliance with treatment and minimise the psychotic symptoms they experience.

CHAPTER SEVEN: CONCLUSIONS

7.1 SUMMARY OF THESIS

Schizophrenia is a serious and enduring mental disorder that has a lifetime prevalence of one percent. Antipsychotic medication has established efficacy in treating many of the symptoms of schizophrenia. However, non-compliance is common and is observed in around 42% of patients. The reasons for poor adherence are complex and an extensive list of factors is reported within the literature. The most important appear to be patients' insight into their illness, their beliefs about treatment and the side effects they experience from their medication. A variety of interventions to improve compliance have been tested and shown to be effective. These include compliance therapy (Kemp *et al.*, 1996; 1998) and behavioural tailoring (Boczkowski *et al.*, 1985). The effective assessment and management of antipsychotic side effects may also be effective in improving compliance but this hypothesis has not been tested.

A substantial proportion of patients with schizophrenia are treated in the community by mental health nurses (CPNs). A number of non-randomised controlled trials have demonstrated that training is an effective method of providing CPNs with the skills they need to deliver new interventions (such as family work; Brooker *et al.*, 1994). Potentially a training course that develops CPNs' knowledge and skills in helping patients manage their medication more effectively may improve compliance with antipsychotic medication. In turn improved compliance should result in patients experiencing fewer psychotic symptoms.

The most important research question to address was whether medication management training would lead to a reduction in patients' psychopathology. However, a preliminary investigation was first necessary to quantify deficits in current CPN practice and explore the impact that recent training initiatives (such as Thorn) have had. If a need for training was identified then a course could be developed and piloted to test the impact of training on CPNs' clinical skills and knowledge. If this training was piloted and then shown to be useful, further investigation of the impact of training on patients' clinical outcomes would be warranted.

A national survey of 250 CPNs and Thorn graduates was conducted with an adjusted response rate of 54%. Respondents were shown to be representative of CPNs currently working in England and Wales at the time of the last national survey (Brooker and White, 1997). CPNs and Thorn graduates both reported that helping patients manage their medication was an important part of their role. Significantly more Thorn graduates than CPNs reported using valid measures of psychopathology and side effects. Both groups identified a need for further training in medication management interventions such as assessing side effects and enhancing compliance. The results of this survey were broadly consistent with previous studies (Bennett *et al.*, 1995; Gray 1998b) and suggest that CPNs would benefit from and are receptive to training in medication management.

Based on the evidence presented in chapter one, data from the survey (chapter two), and advice from a multidisciplinary group of experienced academics and clinicians, a

curriculum for a brief 80 hour medication management course was developed. The core components were:

1. Assessment of factors likely to affect compliance.
2. Compliance therapy.
3. Behavioural tailoring.
4. Patient education.
5. Psychopharmacology.
6. Clinical Supervision.

This curriculum was piloted in a within subjects repeated measures uncontrolled study. Fifteen CPNs attended an 80 hour ten day medication management course. Clinical skills and knowledge were assessed pre- and post-training. The primary outcome measure was the Cognitive Therapy Scale (CTS; Vallis *et al.,* 1986; Dobson *et al.,* 1985) a ten item, blind rated, measure of clinical skills. Trainees were broadly representative of CPNs working in England and Wales. Post-training, there were significant improvements in CTS total scores. Improvements in trainees' knowledge about medication management were also found and it was reported that the course was acceptable and relevant to CPNs' clinical practice.

From this pilot investigation and the findings presented in chapter two there was sufficient evidence to warrant a randomised controlled trial to address the central research question identified in chapter one:

- Does medication management training for CPNs improve patients' clinical outcomes?

Based on a power calculation, sixty CPNs were recruited to the trial, organised into twelve geographical clusters to minimise contamination, and randomised into either an experiential or waiting list control group. Each CPN identified two patients on their caseload who met the inclusion/exclusion criteria. A research worker, who was blind to the training condition, assessed these patients at baseline (week 0), and again after 26 and 52 weeks. CPNs in the experimental group received training after the baseline assessment. CPNs in the waiting list control group continued with their standard practice and then received training following the week 26 assessment. The primary aim was to determine whether medication management training would produce significant improvements in patients' psychopathology (as measured using the PANSS) because of enhanced treatment adherence (as measured using the DAI-30).

Complete data were available for 52 trainees at baseline, 42 at the week 26 assessment and 29 at the week 52 assessment. An analysis of the demographic and clinical profile of the CPNs and patients who left the trial suggests that this happened by chance (e.g. CPNs leaving the NHS Trust where the trial was conducted). CPNs who entered the trial were representative of community nurses currently working in England and Wales (Brooker and White 1997). Patients were also representative of those currently in receipt of mental health services in the UK.

The main findings of the randomised controlled trial were:

1. Training was effective in enhancing CPNs' medication management knowledge and skills.
2. At the week 26 assessment, 48% of CPNs in the experimental group and 26% in the waiting list control group showed improvements in the primary outcome measures. Following training a similar proportion of CPNs in the control group showed improvements in the primary outcome measures.
3. Improvements in psychopathology were maintained in the experimental group at the week 52 assessment.
4. Training had no significant effect on patients' insight into their illness.
5. Mean prescribed dose of antipsychotic medication (in chlorpromazine equivalents) was high throughout the trial and did not change significantly in either group.
6. Patients experienced a moderate degree of side effects for the duration of the trial.

This randomised controlled trial establishes for the first time, using robust methodology, that CPNs can be trained to deliver an intervention derived from the research evidence. The methodology used in this trial should form the foundation of more robust trials that evaluate the impact of training interventions in many areas of health care. Only by developing training interventions with established efficacy can evidence based interventions be disseminated throughout the NHS allowing nurses to work effectively towards improving the mental health of the nation.

REFERENCES

Adams S. G. and Howe J. T. (1993) Predicting medication compliance in a psychotic population. *Journal of Nervous and Mental Disease,* 181, 9, 558-560.

Adler L. A. Angrist B. Rieter S. et al (1989) Neuroleptic induced akathisia: a review. *Psychopharmacology,* 97, 1-11.

Amador X. F. Flaum M. Andreason N. C. et al (1996) Awareness of illness in schizophrenia and schizoaffective disorder. *Archives of General Psychiatry,* 51, 9, 826-836.

Appelbaum P. S. and Gutheil T. G. (1980) Drug refusal: a study of psychiatric inpatients. *American Journal of Psychiatry,* 137, 340-346

Ayd F. J. (1961) A survey of drug induced extrapyramidal reactions. *JAMA,* 175, 1054-1060.

Babiker I. E. (1986) Non-compliance in schizophrenia. *Psychiatric Developments,* 4, 329-337.

Baker, L. A. Cheng I. Y. Amara I. B. (1983) The withdrawal of benzotropine mesylate in chronic schizophrenic patients. *British Journal of Psychiatry,* 143, 584-590.

Barnes T. R. E. and McPhillips M. A. (1996) Antipsychotic induced extrapyramidal symptoms. Role of anticholinergic drugs in treatment. *CNS Drugs,* 6, 4, 315-330.

Barrowclough C. Tarrier N. Watts S. et al (1987) Assessing the functional value of relatives' knowledge about schizophrenia: a preliminary report. *British Journal of Psychiatry,* 151, 1-8.

Bartko G. Herczeg I and Zador G. (1988) Clinical symptomatology and drug compliance in schizophrenic patients. *Acta Psychiatrica Scandinicica,* 77, 74-76.

Beasley C. M. Hamilton s. H. Crawford A-M. et al (1997) Olanzapine versus haloperidol: acute phase results of the international double-blind olanzapine trial. *European Neuropsychopharmacology,* 7, 125-137.

Bebbingtton P. Wilkins S. Jones P. et al (1993) Life events and psychosis. Initial results from the Camberwell collaborative psychosis study. British Journal of Psychiatry, 162, 72-79.

Bebbington P. and Kuipers E. (1994) The predictive utility of expressed emotion in schizophrenia: an aggregate analysis. *Psychological Medicine,* 24, 4, 707-718.

Bell M. Milstein R. Beam-Goulet J. et al (1992) The positive and negative syndrome scale and the brief psychiatric rating scale: reliability comparability and predicative validity, *Journal of Nervous Mental Disease,* 180, 723-728.

Bennett J. Done J. Hunt B et al (1995) Assessing the side effects of antipsychotic drugs: A survey of CPN practice. *Journal of Psychiatric and Mental Health Nursing,* 2, 3, 315-330.

Bermanzohn P. C. and Stris S. G. (1994) Noncompliance with anti-Parkinsonian medication in neuroleptic-treated schizophrenic patients: Three case studies of an unreported phenomenon. *Journal of Clinical Psychiatry,* 55, 488-491.

Bigliani V. and Pilowsky L. (1999) *In vivo* neuropharmacology of schizophrenia. *British Journal of Psychiatry,* 174 (supplement 38), 23-33.

Bigliani, V., Mulligan R. S. Acton P. D. et al (1998) Preliminary results: D_2/D_3 like receptor binding in temporal cortex and striatum in sertindole and olanzapine treated patients. *Journal of Nuclear Medicine,* 39, 319.

Birchwood M. Smith V. Drury V. et al (1994) A self-report insight scale for psychosis: reliability, validity and sensitivity to change. *Acta Psychiatrica Scandinivica,* 89, 62-67.

Blackwell B. (1996) From compliance to alliance: a quarter century of research. *Netherlands Journal of Medicine,* 48, 140-149.

Bland, M (1994) *An introduction to medical statistics.* Oxford medical publications, Oxford.

Bleuler M. (1974) The long-term course of schizophrenic psychoses. *Psychological Medicine,* 4, 244-254.

Boczkowski J. A. Zeichner A. and De Santo N. (1985) Neuroleptic compliance among chronic schizophrenic outpatients: an intervention outcome report. *Journal of Consulting and Clinical Psychology,* 53, 666-671.

Boodhoo J. A. and Sandler M. (1991) Anticholinergic antiParkinsonian drug in psychiatry. *British Journal of Hospital Medicine,* 46, 167-169.

Borrison R. L. (1985) Amantadine in the management of extrapyramidal side effects. *Clinical Neuropharmacology,* 6, (supplement 1), S57-S63.

Brooker C. Tarrier N. Barrowclough C. et al (1992a) Training community psychiatric nurses for psychosocial intervention. Report of a pilot study. *British Journal of Psychiatry,* 160, 836-844.

Brooker C. Barrowclough C. Tarrier N. (1992b) Evaluating the impact of training community psychiatric nurses to educate relatives about schizophrenia. *Journal of Clinical Nursing*, 1, 19-25.

Brooker A. and Butterworth C. (1993) Training in psychosocial intervention: the impact of the role of community psychiatric nurses. *Journal of Advanced Nursing,* 18, 583-590.

Brooker C. Fallon I. Butterworth A. et al (1994) The outcome of training community psychiatric nurses to deliver psychosocial intervention. *British Journal of Psychiatry,* 165, 222-230.

Brooker C. and White E. (1997) *The fourth quinquennial national community mental health nursing census of England and Wales.* University of Manchester, Manchester.

Brown C. S. Wright R. G. and Christensen D. B. (1987) Association between type of medication instruction and patient knowledge, side effects and compliance. *Hospital and Community Psychiatry,* 38, 55-60.

Buchanan A. (1992) A two-year prospective study of treatment compliance in patients with schizophrenia. *Psychological medicine,* 22, 787-797.

Casey D. E. and Keepers G. A. (1988) Neuroleptic side effects: Acute extrapyramidal syndromes and tardive dyskinesia. In: Casey D. E. and Christensen A. V. (Eds) *Psychopharmacology: Current Trends.* Springer, Berlin.

Casey D. E. (1996) Extrapyramidal syndromes. Epidemiology, pathophysiology and the diagnostic dillemma. *CNS Drugs,* 5 (supplement 1), 1-12.

Chadwick P. Trower P. (1996) Cognitive therapy for punishment paranoia: a single case experiment. *Behaviour Research and Therapy,* 34, 4, 351-356.

Chan D. W. (1984) Medication compliance in a Chinese psychiatric outpatient setting. *British Journal of Medical Psychology,* 57, 81-89.

Chouinard G. Annable L. Ross-Chouinard A. et al (1988) A five year prospective longtudinal study of tardive dyskinesia. *Journal of Clinical Psychopharmacology,* 8, S21-S26.

Churchill D. N. (1985) Compliance how to measures it. *Medicine of Canada,* 40, 1068-1070.

Ciompi L. (1980) Catamnestic long-term study of the course of life and ageing in schizophrenics. *Schizophrenia Bulletin,* 6, 606-618.

Claghorn J. Chapman J. P. Abuzzahab F. S. et al (1987) The risks and benefits of clozapine versus chlorpromazine. *Journal of Clinical Psychopharmacology,* 7, 377-384.

Clozapine Study Group (1993) The safety and efficacy of clozapine in severe treatment-resistant schizophrenic patients in the UK. *British Journal of Psychiatry,* 163, 150-154.

Cochran S. D. and Gitlin M. J. (1988) Attitudinal correlates of lithium compliance in bipolar affective disorders. *Journal of Nervous and Mental Disorders,* 176, 457-464.

Cook P. E. Dermer S. W. McGurk T. et al (1986) Fatal overdose with amantadine. *Canadian Journal of Psychiatry,* 31, 757-758.

Cramer J. A. and Rosenheck R. (1998) Compliance with medication regimens for mental and physical disorders. *Psychiatric Services*, 49, 196-201.

Creese I. Burt D. R. and Snyder S. H. (1976) Dopamine receptor binding predicts clinical and pharmacological potencies of antipsychotic drugs. *Science,* 192, 481-483.

David A. (1990) Insight. *Lancet,* 6423, 618, 782.

Day J. C. Wood G. Dewey M. Bentall R. P. (1995) A self-rating scale for measuring neuroleptic side-effects. Validation in a group of schizophrenic patients. *British Journal of Psychiatry,* 166, 650-653.

Day R. Neilson J. A. Korton A. et al (1987) Stressfull life efvents preceding the acute onset of schizophrenia: a cross-national study from the World Health Organisation. Cultural and Medical Psychiatry, 11, 2, 123-206.

DeQuardo J. R. (1998) Pharmacologic treatment of first-episode schizophrenia: early intervention is key to outcome. *Journal of Clinical Psychiatry,* 59, supplement 19, 9-17.

Department of Health (1999) *The National Service Framework for Mental Health.* The Stationary Office, London.

Desai N. (1999) Switching from depot antipsychotics to risperidone: results of a study of chronic schizophrenia. *Advances in therapy,* 16, 2, 78-88.

Devane S. M. Haddock S. Lancashire S. et al (1998) The clinical skills of community psychiatric nurses working with patients who have severe and enduring mental health problems: an emperical analysis. *Journal of Advanced Nursing,* 27, 253-260.

DiMascio A. Bernardo D. L. Greenblatt D. J. et al (1976) A controlled trial of amantadine in drug induced extrapyramidal disorders. *Archives of General Psychiatry,* 33, 599-602.

Dobson K. S. Shaw B. F. Vallis T. M. (1985) Reliability of a measure of the quality of cognitive therapy. *British Journal of Clinical Psychology,* 24, 4, 295-300.

Drachman D. A. (1977) Memory and cognitive function in man: does the cholinergic system have a specific role? *Neurology,* 27, 8, 783-790.

Endicot, J. Spitzer R. L. Fleiss J. L. et al. (1976) The global assessment scale. *Archives of General Psychiatry,* 33, 766-771.

Everitt B. (1994) Statistiacal methods for medical investigations. John Wiley, New York.

Everitt B. (1998) Analysis of longitudinal data. *British Journal of Psychiatry,* 172, 7-10.

Everitt B. and Pickles A. (2000) Statistical aspects of the design and analysis of clinical trials. *Imperial College Press, London.*

Fann W. E. and Lake C. R. (1976) Amantadine versus trihexyphenidyl in the treatment of neuroleptic induced Parkinsonism. *Archives of General Psychiatry,* 33, 599-602.

Farde L. Nordstrom A. L. Nyberg S. et al (1992) D_1-, D_2 and 5-HT2-receptor occupancy in clozapine treated patients. *Journal of Clinical Psychiatry,* 55 (supplement B), 67-69.

Flischhacker W. W. (1991) Propranolol for fluoxetine induced akathisia. *Biological Psychiatry,* 30, 531-532.

Flischhacker W. W. Meise U. Günther et al (1994) Compliance with antipsychotic drug treatment: Influence of side effects. *Acta Psychiatrica Scandinivica,* 382, 11-15.

Gabel W. and Piezcker A. (1985) One-year outcome of schizophrenic patients – the interaction of chronic and neuroleptic treatment. *Psychopharmacology,* 18, 235-239.

Gamble C. Minence K. Leff J. (1994) The effect of family work training on mental health nurses' attitudes to and knowledge of schizophrenia. *Journal of Advanced Nursing,* 19, 893-396.

Gardos G. Cole J. O. Tarsy D. (1978) Withdrawl syndrome associated with antipsychotic drug treatment: Influence of side effects. *American Journal of Psychiatry,* 135, 1321-1324.

Gask L. (1999) Acquisition of clinical skills. *Advances in Psychiatric Treatment,* 5, 4, 31-316.

Gerlach J. and Casey D. E. (1988) Tardive dyskinesia. *Acta Psychiatrica Scandinivica,* 77, 369-378.

Goff D. C. Arana G. W. Greenblatt D. J. (1991) The effect of benztropine on haloperidol induced dystonia, clinical efficacy and pharmacokinetics: a prospective, double blind trial. *Journal of Clinical Psychopharmacology,* 11, 2, 106-112.

Gomez J. C. Sacristan J. A. Hernandez J. (2000) The safety of olanzapine compared with other antipsychotic drugs: results of an observational prospective study in patients with schizophrenia (EFESO Study). Pharcoepidemiologic Study of Olanzapine in Schizophrenia. *Journal of Clinical Psychiatry*, 61, 335-343.

Gotesman H. McGuffin P. Farmer A. E. (1987) Clinical genetics as clues to the 'real' genetics of schizophrenia. A decade of modest gains whilst playing for time. *Schizophrenia Bulletin,* 13, 1, 23-47

Gournay K. and Brooking J. (1994) Community psychiatric nurses in primary health care. *British Journal of Psychiatry,* 165, 231-238.

Gournay K. Birley J. (1998) Thorn: a new approach to mental health training. Nursing Times, 94, 49, 54-5.

Gournay K. Denford L. Parr A-M. Newel R. (2000) British nurses in behavioural psychotherapy a 25 year follow-up. *Journal of Advanced Nursing,* 32, 2, 343-351.

Gournay K. Brooker C. (2000) *Mapping the capacity of the English University system to deliver NSF training priorities.* Report to the NHS(E), Leeds

Gray R. Smedley N. Miller K. Vearnals S. (1995) Health education needs of people with schizophrenia taking clozapine. *Journal of Clinical Nursing*, 5, 333-334.

Gray R. Smedley N. Thomas B (1997) The administration of PRN medication by mental health nurses. *Journal of Psychiatric and Mental Health Nursing,* 4, 55-57.

Gray R. (1998a) Effective dosing in the use of antipsychotics for treatment of acute schizophrenia. *Mental Health Care*, 1, 9, 303-304.

Gray R. (1998b) Primary care of schizophrenia: What are the roles of practice and community psychiatric nurses. *Community Mental Health,* 1, 4, 5-7.

Gray R. (1999) Antipsychotics, side effects and effective management. *Mental Health Practice,* 2, 7, 14-20.

Gray R. (2000) Does patient education enhance compliance with clozapine? A preliminary investigation. *Journal of Psychiatric and Mental Health Nursing,* 7, 285-286.

Guy W. (1976) *Assessment manual for psychopharmacology.* Department of Education and Welfare, Washington DC.

Hawton K. and Kirk J. (1996) Problem Solving. In: Hawton K. et al. *Cognitive behaviour therapy for psychiatric problems. A practical guide.* Oxford Medical Publication, Oxford.

Haynes R. B. (1976) A critical review of the 'determinant' of patients compliance with therapeutic regimens. In *Compliance with therapeutic regimens.* D. L. Sackett and R. B. Haynes (eds) John Hopkins University Press, Baltimore.

Haynes R. B. Montague P. Oliver T. et al (1999) *Interventions for helping patients follow prescription for medications (Cochrane Review).* In: The Cochrane Library, Issue 4, Oxford: Update Software.

Hayward P. Chan N. Kemp R. et al (1995) Medication self management: a preliminary report of an intervention to improve medication compliance. *Journal of Mental Health,* 4, 511-517.

Helgason L. (1990) Twenty year follow-up of first psychiatric presentation for schizophrenia: what could have been prevented? *Acta Psychiatrica Scandinivica,* 81, 231-235.

Hogan T. P. Awad A. G. and Eastwood R. (1983) A self-report scale predictive of drug compliance in schizophrenic: Reliability and discriminative validity. *Psychological Medicine, 13, 177-183.*

Jablensky A. Sartorius M. Ernberg G. et al. (1992) Schizophrenia: manifestations, incidence and course in difference cultures. A World health organisation ten-country study. *Psychological Medicine Monographs Supplement,* 20, 1-97.

Jacobson N. Wilson L And Tupper C. (1988) The clinical significance of treatment gains resulting from exposure-based interventions for agoraphobia: a re-analysis of outcome data. *Behaviour Therapy,* 19, 539-552.

Jacobson N. and Traux P. (1991) Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology,* 59, 12-19.

Jellinek T. Gardos G. Cole J. O. (1981) Adverse effects of antiparkinson drug withdrawal. *Archives of General Psychiatry,* 35, 483-489.

Jones P. Rodgers B. Murray R. et al (1994) Child development risk factors for adult schizophrenia in the British 1946 birth cohort. *Lancet,* 344, 1398-1402.

Jones SH. Thornicroft G. Coffey M. Dunn G. (1995) A brief mental health outcome scale-reliability and validity of the Global Assessment of Functioning (GAF). British Journal of Psychiatry.166, 5, 654-9

Kabes J. Sikora J. Pisvejc J. et al (1982) Adverse effects of antiParkinson drug withdrawl. *Archives of General Psychiatry,* 17, 185-192.

Kane J. Honigfeld G Singer J. Meltzer H. (1988) Clozapine for the treatment-resistent schizophrenic. A double-blind comparison with chlorpromazine. *Archives of General Psychiatry,* 45, 789-796.

Kane J. M. (1989) Management strategies for the treatment of schizophrenia. *Journal of Clinical Psychiatry,* 60, supplement 12, 13-17.

Kapur S. and Remington G. (1996) Serotonin-dopamine D_2 receptor occupancy with low dose haloperidol treatment: A PET study. *American Journal of Psychiatry,* 153, 466-473.

Kay S. R. Opler L. A. and Fiszbein A. (1986) Significance of positive and negative syndromes in chronic schizophrenia. *British Journal of Psychiatry,* 149, 439-448.

Kay S. R. Fiszbein A. and Opler L A. (1987) The positive and negative syndrome scale (PANSS) for schizophrenia. *Schizophrenia Bulletin,* 13, 261-276.

Kay S. R. Opler l. A. and Lindenmayer J. P. (1988) Reliability and validity of the positive and negative syndrome scale for schizophrenia. *Psychiatry Research,* 23, 99-110.

Kay S. Opler L. Lindenmayer J. P. (1989a) the positive and negative syndrome scale (PANSS): rationale and standardisation. *British Journal of Psychiatry,* 155 (supplement 7), 59-65.

Kay S. R. and Singh M. M. (1989b) The positive and negative distinction in drug-free schizophrenic patients. *Archives of General Psychiatry,* 46, 711-718.

Keepers G. A. Clappison V. J. Casey D. E. (1983) Initial anticholinergic prophylaxis for neuroleptic induced extrapyramidal syndromes. *Archives of General Psychiatry*, 40, 1113-1117.

Kemp R. and David A. (1996) Psychosis: Insight and compliance. *Current Opinion in Psychiatry*, 8, 6, 357-361

Kemp R. and David A. (1997) Reasoning and Delusions. *British Journal of Psychiatry,* 170, 398-405.

Kemp R. Hayward P. Applewhaite G. et al (1996) Compliance therapy in psychoatic patients. Randomised controlled trial. *British Medical Journal,* 312, 345-349.

Kemp R. Hayward P. David A. (1997) *Compliance therapy manual.* The Bethlem and Maudsley NHS Trust, London.

Kemp R. Kirov G. Everitt P. et al (1998) Randomised controlled trial of compliance therapy. 18-month follow-up. *British Journal of Psychiatry,* 172, 413-419.

Kisling W. (1994) Compliance, quality assurance and standards for relapse prevention in schizophrenia. *Acta Psychiatrica Scandiviavica,* 89 (supplement 382), 16-24.

Korsgaard S. and Friis T. (1986) Effects of manserin in neuroleptic-induced Parkinsonism. *Psychopharmacology,* 88, 109-111.

Kramer, M. S. Gorkin R. A. DiJohnson C. et al (1988) Propranol in the treatement of neuroleptic induced akathisia (NIA) in schizophrenia: a double-blind placebo controlled study. *Biological Psychiatry,* 24, 823-827.

Krawiecka M. Goldberg D. Vaughn M. et al (1977) A standardised psychiatric assessment scale for rating chronic psychotic patients. *Acta Psychiatrica Scandinavica,* 55, 299-308.

Lancashire S. Haddock G. Tarrier N. et al (1997) The impact of training community psychiatric nurses to use psychosocial interventions with people who have severe mental health problems. *Psychiatric Services,* 48, 39-41.

Lancashire S. Craig T. Haddock G. et al (under review) Training community psychiatric nurses in psychosocial interventions for psychotic disorders: Clinical and social outcomes for patients. Journal of Social Psychiatry.

Lavin, M. R. and Rifkin A. (1991) Prophylactic antiparkinson drug use: I. Initial prophylaxis and prevention of side effects. *Journal of Clinical Pharmacology,* 31, 763-768.

Lecompte D. and Pelc I. (1996) A cognitive-behavioural programme to improve compliance with medication in patients with schizophrenia. *International Journal of Mental Health,* 25, 51-56.

Lin H. F. Spiga, R. Fortsch W. (1979) Insight and adherence to medication in chornic schizophrenics. *Journal of Clinical Psychiatry,* 40, 430-432.

Linjaerde O. Ahlfors U. G. Bech P. et al. (1987) The UKU side effects rating scale. *Acta Psychiatrica Scandinivica,* 76 (supplement 334), 83-94.

Lukoff D. Nuechterlein K. H. and Ventura J. (1996) Manual for the expanded BPRS. *Schizophrenia Bulletin,* 12, 594-602.

McEovy J. P. Apperson L. J. Applebaum P. S. et al (1989) Insight in schizophrenia. Its relationship to acute psychopathology. *Journal of Nervous and Mental Disease,* 177, 43-47.

McGlashan T. H. (1998) Early detection and intervention of schizophrenia: rationale and research. *British Journal of Psychiatry,* 172, 33, 3-6.

McNeil T. F. (1995) Perinatal risk factors and schizophrenia: selective review and methodological concerns. *Epidemiological Review,* 17, 107-112.

Macpherson R. Jerrom B. Hughes A. (1996a) A controlled study of education about drug treatment in schizophrenia. *British Journal of Psychiatry,* 168, 709-717.

Macpherson R. Jerrom B. and Hughes A. (1996b) Relationship between insight, educational background and cognition in schizophrenia. *British Journal of Psychiatry,* 168, 718-722.

Marder S. R. Mebane A. Chiem C. et al (1983) A comparison of patients who refuse and consent to neuroleptic treatment. *American Journal of Psychiatry,* 140, 470-472.

Marder S. R. Davis J. M. and Chouinard G. (1997) The effects of risperidone of the five dimensions of schizophrenia derived by factor analysis: combined results of the North American trials. *Journal of Clinical Psychiatry,* 58, 12, 538-546.

Marder S. R. (1999) Antipsychotic drugs and relapse prevention. *Schizophrenia Research,* 35, supplement S87-S92.

Marks I. M. Hallam R. S. Connolly J. Philpott R. (1977) *Nursing in behavioural psychotherapy.* Royal College of Nursing, London.

Matted J. A. (1989) Clozapine for refractory schizophrenia: an open study of 14 patients treated for up to two years. *Journal of Clinical Psychiatry,* 50, 38I. M. 9-391.

Meichenbaum D. and Tusk D. C. (1987) *Facilitating treatment adherence: A practitioner's guidebook.* Plenum Press, New York.

Meltzer H. Y. Bastani B. Kwon K. Y. et al (1989) A prospective study of clozapine in treatment-resistent schizophrenic patients I: preliminary report. *Psychopharmacology,* 99, S68-S72.

Mindham R. H. S. (1976) Assessment of drug induced extrapyramidal reactions and of drugs given for their control. *British Journal of Clinical Pharmacology,* supplement, 395-400.

Mindham R. H. S. Lamb P. Bradley R. (1977) A comparison of piribedil, procyclidine and placebo in the control of phenothiazine-induced Parkinsonism. *British Journal of Psychiatry,* 130, 581-585.

Moore (1999) Behavioural pharmacology of the new generation of antipsychotic agents. *British Journal of Psychiatry,* 174, supplement 38, 5-11

Mutsatsa S. Ritter S., Rabe-Hesketh, S. et al. (in submission) Side effects and the treatment of schizophrenia with antipsychotic medication – a prospective logitudinal study. Journal of Mental Health

Nestelbaum Z. Siris S. G. Rifkin A. et al (1986) Exacerbation of schizophrenia associated with amantadine. *American Journal of Psychiatry,* 143, 1170-1171.

Newton K. L. Murthy R. Qureshi J. (1996) Antipsychotic prescribing in light of the consensus statement of the college. *Psychiatric Bulletin,* 21, 408-410.

Nordstrom A. L. Farde I. Weisel F. A. et al (1993) Positron emission tomographic analysis of central D_1 and D_2 dopamine receptor occupancy in patients treated with classical neuroleptics and clozapine: Relation to extrapyramidal side-effects. *Archives of General Psychiatry,* 49, 538-544.

O'Callaghan F. Sham P. C. Takie N. et al (1994) The relationship of schizophrenic births and infectious diseases. *British Journal of Psychiatry,* 165, 3, 353-356.

Opler L. A. Caton C. L. Shrout P. (1994) Symptom profiles and homelessness in schizophrenia. *Journal of Nervous and Mental Disease*, 182, 3, 174-178.

Overall J. E. and Gorham D. R. (1962) Brief Psychiatric Rating Scale. *Psychological Reports,* 10, 799-812.

Owen Jr. R. R. Beake B. J. Marby D. et al (1989) Response to clozapine in chronic psychotic patients. *Psychopharmacology Bulletin,* 25, 253-256.

Parkin D. M. Henney C. R. Quirk J. and Crooks J. (1976) Deviation from prescribed drug treatment after discharge from hospital. *British Medical Journal,* 2, 6037, 686-688.

Peralta V. and Cuesta M. J. (1994) Psychometric properties of the positive and negative syndrome scale (PANSS) in schizophrenia. *Psychiatry Research,* 53, 31-40.

Percudani M. Fattore G. Galletta J. et al (1999) Health care costs of therapy-refractory schizophrenic patients treated with clozapine: a study in a community psychiatric service in Italy. *Acta Psychiatrica Scandinavica,* 99, 4, 274-280.

Peuskens J. on behalf of the risperidone study group (1995) Risperidone in the treatment of patients with chronic schizophrenia: A multi-national, multi-centre, double-blind, parallel-group study versus haloperidol. *British Journal of Psychiatry,* 166, 712-726.

Pilowsky L. S. Costa D. C. Ell P. J. et al (1992) Clozapine, single photon emission tomography and the D_2 dopamine receptor blockade hypothesis of schizophrenia. *Lancet,* 340, 199-202.

Pilowsky L. S. Costa D. C. Ell P. J. et al (1993) Antipsychotic medication D_2 dopamine blockade receptor blockade and clinical response: a 123I IBZM SPET (single photon emission tomography) study. *Psychological Medicine,* 23, 791-797.

Piatkowska O and Farnill D. (1992) Medication – compliance or alliance? A client-centred approach to increasing adherence. In: Kavanagh D. J. Schizophrenia an overview and practical handbook, Chapman and Hall, London.

Pocock S. J. (1983) *Clinical trials a practical approach.* John Wiley, Chichester

Quitkin F. Riftkin A. Kane J. M. et al (1978) Long action versus injectable antipsychotics drugs in schizophrenics. A one year double-blind comparison in multiple episode schizophrenics. *Archives of General Psychiatry,* 35, 889-892.

Rego M. D. and Geller E. L. (1989) Mania secondary to amantadine treatment of neuroleptic-induced hyperprolactinemia. *Journal of Clinical Psychiatry,* 50, 143-144.

Renton C. A. Affleck J. W. Carstairs G. M. et al (1963) A follow-up of schizophrenic patients in Edinburgh. *Acta Psychiatrica Scandinivica,* 39, 548-600.

Rifkin L. Lewis S. Jones P. et al (1994) Low birth weight and schizophrenia. *British Journal of Psychiatry,* 165, 357-362.

Schulz S. C. Camlin K. L. Berry S. A. Jesberger J. A. (1999) Olanzapine safety and efficacy in patients with borderline personality disordered and comorbid dysthimia. *Biological psychiatry,* 46, 10, 1429-1435.

Scott J. Jennings T. Standard S., et al., (1991) The impact of training in problem-based interviewing on the detection and management of psychological problems presenting in primary care. *British Journal of General Practice,* 49, 443, 441-445.

Seltzer A. Roncari I. and Garfinkel P. (1980) Effect of patient education on medication compliance. *Canadian Journal of Psychiatry,* 25, 638-645.

Shepherd M. Watt D. Falloon I et al. (1989) The natural history of schizophrenia: a five year follow-up study of outcome and prediction in a representative sample of schizophrenics. *Psychological Medical Monograph Supplement,* **15,** 1-46.

Simpson G. M. and Angus J. W. S. (1970) Drug-induced extrapyramidal disorders. *Acta Psychiatric Scandinavica,* 45 (supplement 212), 11-19.

Smith J. and Birchwood M. (1987) Relatives and patients as partners in the management of schizophrenia. *British Journal of Psychiatry,* 156, 654-660.

Smith J. Birchwood M. Haddrell A. (1992) Informing people with schizophrenia about their illness: The effect of residual symptoms. *Journal of Mental Health,* 1, 61-70.

Smith J. and Birchwood M. (1992) The influence of ethnicity and family structure on relapse in first-episode schizophrenia. A comparison of Asian, Afro-Caribbean and white patients. 161, 783-790.

Swofford C. Kasckow D. Scheller –Gilkey G. *et al.* (1996) Substance use: a powerful predictor of relapse in schizophrenia. *Schizophrenia Research,* 20, 145-151.

Stenson R. L. Donlan P. T. and Meyer J. E. (1976) Comparison of benztropine mesylate and amantadine HCI in neuroleptic induced extrapyramidal symptoms. *Comprehensive Psychiatry,* 17, 763-768.

Stricker S. K. Amdur M. Dincin J. (1986) Educating patients about psychiatric medication, failure to enhance compliance. *Psychosocial Rehabilitation,* 4, 15-28.

Taylor D. McConnell D. McConnell H. et al (1999) *The Bethlem and Maudsley NHS Trust Prescribing Guidelines 5th Edition.* Martin Dunitz, London.

Vallis T. M. Shaw B. F. Dobson K. S. (1986) The cognitive therapy scale: psychometric properties. *Journal of Consulting and Clinical Psychology, 54, 3, 381-385.*

van Putten T. (1974) Why do schizophrenic patients refuse to take their medication? *Archives of General Psychiatry,* 31, 67-72.

van Putten T. May P. R. Marder S. R. and Wittman L. A. (1976) Drug refusal in schizophrenia and the wish to be crazy. *Archives of General Psychiatry,* 33, 1443-1446.

van Putten T. May P. R. A. and Marder S. A. (1984) Akathisia with haloperidol and thiothixene. *Archives of General Psychiatry,* 41, 1036-1039.

Walburn J. Gray R. David A. et al (in submission) A systematic review of patient and nurse attitudes to depot antipsychotic medication. British Journal of Psychiatry.

Wieden P. J. Shaw E. and Mann J. (1986) Causes of neuroleptic non-compliance. *Psychiatric Annals,* 16, 571-578.

Winslow R. S. Stillner V. Coons and Robinson M. W. (1986) Prevention of acute dystonic reactions in patients beginning high-potency neuroleptics. *American Journal of Psychiatry,* 143, 6, 706-710.

Whittington R. and Wykes T. (1996) An evaluation of staff training in psychological techniques for the management of patient aggression. *Journal of Clinical Nursing,* 5, 4, 257-261.

World Health Organisation (1992) *The ICD-10 Classification of mental and behavioural disorder.* World Health Organisation, Geneva.

Wolff R. J.and Colacino D. M. (1961) A preliminary report on the continued post-hospital use of tranquillising drugs. *American Journal of Psychiatry,* 118, 499-503.

Wykes T. Parr AM Landau S. (1999) Group treatment of auditory hallucinations. Exploratory study of effectiveness. *British Journal of Psychiatry,* 175, 180-185.

Yassa R. Iskandar H. and Nastase C. (1988) Propranolol in the treatment of tardive akathisia: a review of two cases. *Journal of Clinical Psychopharmacology,* 8, 283-285.

Zubin J. and Spring B. (1977) Vulnerability: a new view of schizophrenia. *Journal of Abnormal Psychology,* 86, 103-126.

APPENDIX 1

COMMUNITY PSYCHIATRIC NURSING SURVEY

Please complete all sections of the questionnaire marking ☑ where appropriate

Q1. ABOUT YOURSELF

Current job

1. CPN/CMHN ☐
2. Other (you do not need to complete the rest of the questionnaire) ☐

Gender

1. Male ☐
2. Female ☐

Ethnicity

1. White ☐
2. Black ☐
3. Asian ☐
4. Other (specify) ☐ _____

Age

How old are you? _____ years

Year of qualification

In what year did you qualify as a nurse? 19____

Current grade

1. D ☐
2. E ☐
3. F ☐
4. G ☐
5. H ☐
6. I ☐
7. Other specify _____

Qualifications/experience

(Please tick all appropriate boxes)

1. SRN ☐
2. RGN ☐
3. RM (midwife) ☐
4. RSCN ☐
5. RMN ☐
6. RNMH ☐
7. RN (adult) ☐
8. RN (mental health) ☐
9. RN (learning disabilities) ☐
10. RN (child) ☐
11. Diploma ☐
12. Degree ☐
13. Masters ☐
14. MPhil/PhD ☐

Have you attended the THORN course?

1. Yes ☐
2. No ☐

Q2. ABOUT YOUR PRACTICE

How long have you worked as a CPN? _____ years

How many hours do you work each week? _____ hours

The different types of mental disorders commonly seen by CPNs are shown below, divided into four groups. Please indicate how many patients on your caseload have a main diagnosis of the following.

		Number of patients
Group 1	Schizophrenia, dementia, bipolar disorder, severe eating disorders	_____
Group 2	Moderate to severe depression, pure depression, panic disorder, obsessive compulsive disorder	_____
Group 3	Phobia, somatoform disorder, mild eating disorders, post-traumatic stress disorder drug and alcohol problems, chronic fatigue	_____
Group 4	Bereavement, adjustment disorder, mild depression/anxiety	_____
TOTAL NUMBER OF PATIENTS ON YOU CASELOAD		_____

Of the patients on your caseload taking antipsychotic medication, how frequently do you monitor them for side effects?

1. More than once a week ☐
2. Weekly ☐
3. More than once a month ☐
4. Monthly ☐
5. Less than once a month ☐
6. Occasionally ☐
7. Never ☐

Please list which, if any, assessment tools you routinely use to assess antipsychotic side effects.

_____
_____
_____
_____
_____

Please list the antipsychotic side effects that you monitor in your patients (please be a through as possible).

_____
_____
_____
_____
_____

Please list the outcome measures, if any, that you regularly use in your clinical practice (please be as through as possible)

_____
_____
_____
_____
_____

Q3. INTERVENTIONS

Below is list of interventions CPNs are often involved in delivering. Please rate whether you think each is an important part of your role as a CPN.

	Very important	Fairly important	Not important
1. Anxiety management	☐	☐	☐
2. Crisis interventions	☐	☐	☐
3. Monitoring patients' mental state	☐	☐	☐
4. Counselling	☐	☐	☐
5. Relaxation therapy	☐	☐	☐
6. Suicide prevention/dealing with self harm	☐	☐	☐
7. Monitoring the side effects of medication	☐	☐	☐
8. Cognitive behaviour therapy (CBT)	☐	☐	☐
9. Administering depot antipsychotics	☐	☐	☐
10. Ensuring compliance with medication	☐	☐	☐
11. Case management	☐	☐	☐
12. Family work	☐	☐	☐
13. Mental health promotion	☐	☐	☐
14. Risk assessment	☐	☐	☐

Q4. GIVING INFORMATION

Do you give information to patients about schizophrenia?

1. Yes ☐
2. No ☐

Do you give information to patients about antipsychotic medication?

1. Yes ☐
2. No ☐

Do you give information to families about schizophrenia?

1. Yes ☐
2. No ☐

Do you give information to families about antipsychotic medication?

1. Yes ☐
2. No ☐

Q5. TREATMENT

We would like to know your views on the treatment of schizophrenia. Could you please state whether you agree, disagree or are not sure about the following statements?

	Agree	Disagree	Not sure
1. Antipsychotic medication will generally help patients from having a relapse?			
2. Extrapyramidal symptoms are caused by the blockade of serotonin receptors?			
3. Newer (atypical or novel) antipsychotics are better tolerated than older neuroleptics?			
4. Atypical antipsychotics have no affinity for dopamine receptors?			
5. If a patient has not responded to treatment with an antipsychotic it is helpful to increase the dose?			
6. Giving patients information about medication will improve treatment compliance.			
7. Atypical antipsychotics are effective in treating the negative symptoms of schizophrenia.			
8. Clozapine is the only antipsychotic effective in patients with treatment resistant schizophrenia.			

Q6. TRAINING

What training courses have you attended in the last five years?

_____

_____

_____

_____

_____

Which of the following areas would you identify as the most important for training? Please score each item. 9 being the most important, 1 the least important, you may give more than one item the same score.

	Least important								Most important
1. Anxiety management	1	2	3	4	5	6	7	8	9
2. Crisis interventions	1	2	3	4	5	6	7	8	9
3. Monitoring patients' mental state	1	2	3	4	5	6	7	8	9
4. Counselling	1	2	3	4	5	6	7	8	9
5. Relaxation therapy	1	2	3	4	5	6	7	8	9
6. Suicide prevention/dealing with self harm	1	2	3	4	5	6	7	8	9
7. Monitoring the side effects of medication	1	2	3	4	5	6	7	8	9
8. Cognitive behaviour therapy (CBT)	1	2	3	4	5	6	7	8	9
9. Administering depot antipsychotics	1	2	3	4	5	6	7	8	9
10. Ensuring compliance with medication	1	2	3	4	5	6	7	8	9
11. Case management	1	2	3	4	5	6	7	8	9
12. Family work	1	2	3	4	5	6	7	8	9
13. Mental health promotion	1	2	3	4	5	6	7	8	9
14. Risk assessment	1	2	3	4	5	6	7	8	9

Thank you for completing and returning the questionnaire

APPENDIX 2

medication*management*

Course leader
RICHARD GRAY
Section of Psychiatric Nursing
Institute of Psychiatry
De Crespigny Park
London SE5 8AF
T: 020 7848 0139
E: R.Gray@iop.kcl.ac.uk

Course Details

Medication management for psychotic disorders

Category of the Award: 15 credits at level 2 or 3

Length of Study: 10 weeks

Mode of Attendance: Part time

Department in which the Course is Located
Section of Psychiatric Nursing
Institute of Psychiatry
De Crespigny Park
London SE5 8AF

Programme Leader
Richard Gray
Tutor-Practitioner
Section of Psychiatric Nursing
Institute of Psychiatry
De Crespigny Park
London SE5 8AF

Teaching team
Richard Gray
Institute of Psychiatry, London

Euan Hails
Institute of Psychiatry, London

Alan Howard
South London and Maudsley NHS Trust

Sharmine Mir
Clinical Pharmacist
South London and Maudsley NHS Trust

Tim Newey
Service User

Advisory Team (additional to the teaching team)
Professor Kevin Gournay
Institute of Psychiatry, London

Professor Til Wykes
Institute of Psychiatry, London

Lindsey Denford
Institute of Psychiatry, London

Course aims

Overall aim

- By the end of the course the trainee will be proficient in delivering the medication management intervention described in the treatment manual.

Specific course aims

- By the end of the course the trainee will be knowledgeable about the following: 1. The signs, symptoms and aetiology of schizophrenia; 2. Psychopharmacology; 3. Factors affecting compliance; 4. Psychological interventions to enhance compliance.
- By the end of the course the trainees will be skilled in the following: 1. Assessing patients' psychopathology, attitudes towards treatment, insight and antipsychotic side effects; 2. Using a range of medication management and compliance therapy techniques.
- By the end of the course the trainee will have presented one patient they are working with for clinical supervision, demonstrating the application of medication management knowledge and skills in practice.

Teaching methods

A variety of teaching methods will be used and include:

- Formal lectures.
- Group discussion.
- Group exercises.
- Video-ratings of patients.
- Rehearsal of medication management and compliance therapy skills using video role-play.
- Clinical supervision.

Assessments

The course is formatively assessed in the following ways. 1. A multiple choice progress test. 2. Performance on a standardised video role-play task. 3. Reliability in rating patients' mental state.

The summative assessment for the course is a 3000 word case study.

Terms of Reference

1. To ensure the course falls within the remit of Kings College London in terms of its academic profile and conforms to regulations.

2. To ensure that the course is of a high academic standard and compares favourably with its competitors.
3. To enhance and develop the curriculum in line with current trends in the field of mental health research, service provision and policy.
4. To guarantee that entry requirements, teaching methods, assessment procedures and provision of support services are suitable for both the course and the students.
5. To ensure the assessment procedures are fair and open and that marking schemes and the classification system outlined in the course regulations are adhered to.
6. To certify that the award conferred is appropriate for the course and the performance of the student justifies the award.
7. To assure the Education Committee that the management structure within the Department and the course itself is sufficiently well established to address any problems or issues that may arise.
8. To ensure that adequate resources are available for the course.
9. To evaluate current courses and make relevant changes.
10. To consider any other business pertinent to the course or required by the education committee.

Structure and membership of exam boards
These will comply with the regulations of Kings College, London.

Arrangements for obtaining and using student feedback
1. Formal student evaluation of the course will be through an evaluation questionnaire that will be completed at the end of the course.
2. Students will be asked to nominate and will be notified of the name and contact number of a student representative whose role it will be to feedback student views at the course management meetings.
3. At the end of each taught day of the course students will be asked for feedback.
4. Students will be encouraged to approach the Course Co-ordinator at any time with feedback, problems or suggestions with regard to the course itself.

Regulations
All courses conform to Kings College, London regulations. Copies are available on request.

Entry requirements
Appropriate professional qualification i.e. registered nurse (RN), registered mental nurse (RMN), occupational therapist (OT) or equivalent registered qualification in other professions.

Assessment criteria.
Criteria for Marking Written Assignments.

All written submissions will include the following criteria:
- Include a critical review of the relevant literature.
- Focus on one patient the student has been working with.

- Present an anonymous description of the patient so that patient's confidentiality is preserved.
- Include all assessment measures as an appendix.
- Demonstrate the application of an assessment tool/intervention in clinical practice.
- Demonstrate the efficacy of the assessment/intervention in clinical practice.
- Provide evidence of a broad and up to date search of the literature with accurate referencing (using the Harvard system).
- Develop a logical and balanced structure, present coherent lines of argument and offer a conclusion.
- Show initiative in approach, clarity of argument and rigor in handling material.
- Offer analytical comment, critical evaluation and display originality.

The following outline criteria for grading written assessments will be used.

Grade	Standard
70% and above	Excellent. Fulfils the relevant criteria; an exceptional piece of work.
60-69%	Very good. Fulfils most of the relevant criteria to a very high standard
50-59%	Clear pass. Meets the relevant criteria to a Satisfactory standard, or a paper of variable quality which contains some work of a high standard but some which is less than satisfactory
40-49%	Pass. Meets the relevant criteria to a level which is acceptable. Shows limited depth and breadth of understanding
0-39%	Fail. The criteria are not met to an acceptable standard. Knowledge and understanding are not demonstrated or the material is inappropriate to the question.

Failure of an assignment

Students who fail the written assessment will be offered remedial support as required. They will be entitled to two further attempts at any single piece of assessed work. If they are unsuccessful at the third attempt, this will constitute a fail and the practitioner will not receive the award.

Completion of the course

To complete the course and receive an award, participants normally need to have:

1. Attended for the duration of the course. If time taken off for sickness etc, is in excess of 20% of the attendance required, it will be necessary to review the participant's place on the course.
2. Completed all course assessments - formative and summative.
3. Passed the summative assessments.

Negotiated late submission
Students may negotiate with the course leader an extension of the submission date for an assessment if:

1. They are still preparing for a re-attempt at a previous assessment.
2. They have been ill.
3. They have compassionate grounds.
4. They have experienced an emergency e.g. burglary, fire etc.

Requests for extended submission must be put in writing at least one week in advance with an explanation as to why the extension is necessary. Negotiation for the new submission date will be followed by written confirmation of the new deadline, which must be adhered to.

Failure to submit assessments on time
If a student submit assessments late and has not negotiated a later submission date with the course leader, then his/her work will not be marked; this assessment will be regarded as a fail at the first attempt. If a student is unexpectedly absent from the course on the day an assignment is due, it remains his/her responsibility to submit the assignment as soon as possible, either by post, by fax or by hand.

Plagiarism
The offence of plagiarism of written work will result in a fail grade award. Students assigned a fail grade due to plagiarism will be required to be reassessed on that particular assignment.

Irregularities
Any irregularities relating to written assessments will be reported to the head of nursing studies. The head of nursing studies shall consult as appropriate and practicable, for example, with the external examiners and with learners. The head of nursing shall then decide on the action to be taken, which may include reference to the examination board for a decision or for commencement of disciplinary proceedings. The examination board shall, except in cases considered trivial, have reported to them all irregularities and the action taken upon them.

Appeals panel
Appeals related to the conduct of assessments will be examined in relation to and to comply with the regulations of King's College London.

Evaluation of the Course

Internal evaluation.
Within the organisational structure in King's College London, the assessment review group will monitor and ensure quality in all issues relating to the theoretical assessments.

Methods of evaluation and monitoring

1. Written student evaluation, report from student representative, verbal evaluation after taught days.
2. Organisational, using the methods recommended by Kings College, London.

Quality Assurance Mechanisms

Systematic monitoring and evaluation is an established part of practice within King's College, London, as is student evaluation, individual performance appraisal, supervision, peer review, and the organisational audit of educational and clinical standards.

TIMETABLE

Cohort: Trust name, month, year

Day 1 dd/mm/19yy 9:30 Introductions and overview of course 10:00 Multiple choice questionnaire 10:30 Video role play 2:00 Reasons for non-compliance 3:00 Interventions to enhance compliance	Day 2 dd/mm/19yy 9:30 Signs and symptoms of schizophrenia 11:00 Aetiology of schizophrenia 1:00 Assessing symptoms (video rating)
Day 3 dd/mm/19yy 9:30 Assessing symptoms (video rating) 2:00 Role play of structured clinical interview	Day 4 dd/mm/19yy 9:30 Assessing side effects 1:00 Assessing patient's beliefs about medication 2:00 Assessing insight
Day 5 dd/mm/19yy 9:30 Clinical supervision 11:30 Psychopharmacology 2:00 Key skills in medication management role play (reviewing the patient's illness history)	Day 6 dd/mm/19yy 9:30 Clinical supervision 11:30 Psychopharmacology 2:00 Key skills in medication management role play (exploring ambivalence)
Day 7 dd/mm/19yy 9:30 Clinical supervision 11:30 Psychopharmacology 2:00 Key skills in medication management role play (testing patient's beliefs about treatment)	Day 8 dd/mm/19yy 9:30 Clinical supervision 11:30 User experiences 2:00 Key skills in medication management role play (problem solving)
Day 9 dd/mm/19yy 10:00 Clinical supervision 11:30 Dual diagnosis 2:00 Key skills in medication management role play (planning for the future)	Follow-up day dd/mm/19yy 9:30 Clinical supervision updates 12:00 Evaluation of course 2:00 Multiple choice questionnaire 2:30 Video role play

Aims for the course

Spend five minutes thinking about what your personal aims for the course are and list them below. At the start of the course you will be asked to state your aims and this will allow the course content to be modified to meet your learning needs. At the end of the course you will be asked to say whether or not your aims have been achieved.

1. _____

2. _____

3. _____

Evaluation of the course

Were your personal aims achieved?

_____

_____

_____

_____

_____

Clinical supervision

My clinical supervision session will be held on the dd/mm/19yy

Day one

Agenda

9:30 Introductions and overview of the course

10:00 Multiple choice questionnaire

10:30 Video role-play

2:00 Reasons for non-compliance

3:00 Interventions to enhance compliance

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

Homework

It is essential that before next weeks session that you read the following:

- Medication management treatment manual
- Positive and Negative Syndrome Scale

These can be found in your course reading packs.

Think about the patient that you are going to present for your clinical supervision presentation.

Medication management treatment rationale

Richard Gray, Institute of Psychiatry, London

What is the main cause of relapse in patients with schizophrenia?

Richard Gray, Institute of Psychiatry, London

What is the incidence of non-compliance with antipsychotic medication?

Richard Gray, Institute of Psychiatry, London

Compliance rates

Study	Method	n	Comp.
Herz and Melville (1980)	Patient interview	42	60%
Carman et al. (1984)	Urine test	80	35%
Kelley and Scott (1990)	Patient interview	314	50%
Buchanan (1992)	Clinician judge.	61	33%
Flischacaker et al. (1994)	Clinician judge.	151	79%
Adams and Howe (1993)	Patient interview	42	60%
Kapur et al (1992)	Urine test	20	75%

Mean compliance rate approximately 50%

Richard Gray, Institute of Psychiatry, London

Language

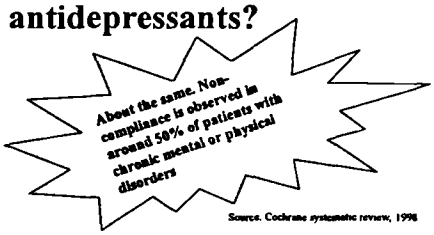
- Compliance
- Adherence
- Concordance
  - Collaborative
  - Working as a team
  - Making decision jointly

Richard Gray, Institute of Psychiatry, London

What proportion of patients who stop antipsychotic medication will relapse?

Richard Gray, Institute of Psychiatry, London

Is compliance better or worse with antidepressants?



Source. Cochrane systematic review, 1998

Non-compliance is the major preventable cause of psychiatric morbidity

How can compliance be enhanced?

Exercise one

List ten reasons why patients stop taking medication

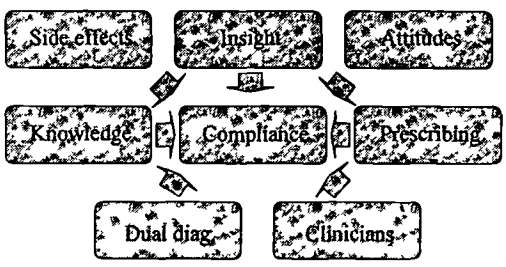
Do side effects affect compliance?

- Mutstava *et al.* in press
  - n=35; ICD-10 schizophrenia; drug naive
    - Current side effects predicted compliance
    - Past side effects didn't
- Gray *et al.* in submission
  - n=78; psychosis;
    - Side effects predict compliance (6% of variance)
- Hierarchy of side effects
- Difficult to do
  - data inconsistent
  - Extrapyramidal symptoms
    - ?especially akathisia (also associated with suicide)
  - Hyperprolactinaemia
  - Weight gain
  - ?sedation
- Study needs to be done but requires large numbers of patients (n=200-300)

Other factors affecting compliance

- Gray et al. in submission; Kemp and David 1996
  - Insight (34% of variance)
- Kane (1983)
  - Clinician behaviour
- Applebaum and Gutheil (1980) Bartko et al. (1988)
  - Psychopathology
- Hogan et al. 1983
  - Beliefs about treatment
- Heyscue et al. (1998)
  - Substance misuse

Compliance



Side effects

- Wieden *et al.* (1986)
  - 26% of patients with akathisia
  - 59% of patients with parkinsonism
- Bennett *et al.* (1995)
  - CPNs ask about 3-4 side effects
- Gray (1998)
  - CPNs didn't ask about important side effects which affect compliance (e.g. sexual dysfunction)

Side effects

- Detection will be improved with the use of assessment tools
  - LUNSERS, Simpson-Angus, AIMS, Barnes
- Nurses aware of the need for more training
- Training limited
  - Problem with Universities
- Many side effects (e.g. EPS, symptomatic hyperprolactinimeia) easily managed
  - *Novel/atypical antipsychotics*

Exercise two

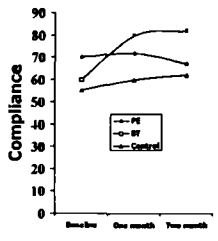
List techniques you have used to improve compliance

RCTs of educational interventions

Author	n	Intervention	Outcome
Strickner *et al.*, (1986)	75	Group patient education	Improved knowledge
Macpherson *et al.*, (1996)	64	Individual patient education	Improved knowledge not compliance
Gray (2000)	44	Individual patient education	No effect on compliance

Behavioural interventions

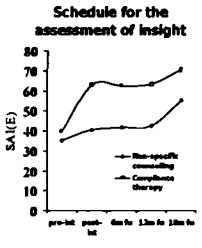
Boczowski *et al.* (1985)



- 36 male chronic patients with schizophrenia
- RCT
- Patients received one session
  - Behavioural tailoring
  - Patient education
  - Control discussion about topic unrelated with medication
- Pill count

Compliance Therapy

(Kemp et al. 1998)



- Randomized controlled trial
- 74 inpatients
  - Compliance Therapy
  - *Non-specific counselling*
- Ratings to 3 months not blind
- Significant improvements
  - Compliance
  - Attitudes
  - Insight
- Time to readmission longer
- Expert study

Summary

- Compliance is a major preventable cause of morbidity
- Medication management interventions are effective
  - Education
  - Detection and management of side effects
  - Careful prescribing
  - Compliance therapy
- Who can deliver medication management interventions
  - CPNs ideally placed
  - Dissemination of research into practice

General skills

(Cognitive therapy scale CTS; Young and Beck, 1980)

- Agenda setting
- Feedback
  - Checking for understanding
  - Summary of main points at end of session
- Understanding
  - Patients internal reality
- Interpersonal effectiveness
- Collaboration
  - Offering choices
  - Functioning as a team
- Pacing and efficient use of time
  - Limiting unproductive discussion
- Guided discovery
  - Socratic questioning
- Strategy for change

Compliance therapy skills

- Reviewing illness history
  - Identifying pattern of illness
  - Discuss negative experiences of treatment
- Beliefs about medication
  - e.g. "medication is poison"; "I don't need to take medication once I feel better"; "medication doesn't help me"
  - Rate belief (0-100%)
  - if less than 100% test the evidence
  - Re-rate the belief

Compliance therapy skills

- Consider pros and cons of treatment
  - "it makes me sleepy .... but also less agitated"
- Target symptom
  - Identified by patient
  - Often indirect
  - Rated on 0-7 scale
- Problem solving
  - Large stages
  - Small steps
- Medication review

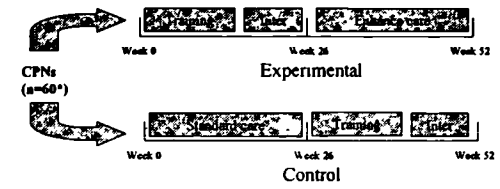
Compliance therapy skills

- Normalising strategies
  - Incidence of mental disorders/symptoms
  - Analogies with physical illnesses
- Consequences of stopping medication
- Long term plans
- Information about illness and treatment

Avoid.....

- Lecturing
- Preaching
- Insisting on diagnostic labeling
- Turning session into a debate
- Asking a series of questions

Design



*Derived from power calculation

Richard Grey, Institute of Psychiatry, London

Conclusion

- Non-compliance is a major problem
  - Need to think about concordance
- Interventions need to be structured and targeted
- Medication management should enhance patients mental health

Richard Grey, Institute of Psychiatry, London

TREATMENT MANUAL

Background

A number of studies have implicated treatment non-compliance (defined as sub-optimal treatment adherence) as a crucial factor in the relapse and rehospitalization of people with schizophrenia (Green, 1998; Haywood et al., 1995). The incidence of non-compliance in people with schizophrenia has been observed in 10% to 80% of patients with psychosis (Babiker, 1986; Young et al., 1986). These variations can be attributed to different treatment settings (e.g. inpatient/outpatient) and methods of measuring compliance. However, it is generally accepted that around 50% of patients will stop taking their medication within a year of antipsychotic medication being started. Interestingly, this is not dissimilar to non-compliance rates in other chronic disorders such as depression (Kemp and David, 1995).

Improved rates of compliance could dramatically reduce relapse. Kissling (1994) suggests that good medication management may improve compliance and could potentially reduce the relapse rates to about 15% (currently around 50% of patients relapse within the first year of remission and about 85% do so within the first five years (Kemp et al., 1997)). In order to develop effective medication management interventions it is first necessary to examine why patients are non-compliant.

Factors affecting compliance

In a comprehensive review of factors associated with non-compliance in psychotic patients, Kemp and David (1995) proposed that variables could be classified into those related to the illness, the treatment and the person. Illness-related factors include lack of insight (Bartko et al., 1988; Lin et al., 1979; McEvoy et al., 1989; van Putten et al., 1976), aspects of psychopathology (for example, paranoia, thought disorder, hostility, delusional beliefs about medication, grandiosity) (Appelbaum and Gutheil, 1980; Hoge et al., 1990; Marder et al., 1983; van Putten, 1974) and cognitive impairment (Geller, 1982; Macpherson et al., 1996; Weiden et al., 1986). Factors associated with treatment include the side-effects of antipsychotics, such as akathisia, akinesia, neuroleptic dysphoria, sexual dysfunction, dystonias, tremor, rigidity and weight gain (Buchanan, 1992; Michaux, 1961; Nelson, 1975; van Putten, 1974; van Putten et al., 1981; Weiden et al., 1986). Person-related factors include the individual's personality and sociocultural background. A number of studies have highlighted that antichemical and antipsychiatry views are common (Angermeyer and Matschinger, 1994). Beliefs about the benefits of 'alternative' cures (such as diet) and the role of self-control and willpower in overcoming the illness are also prevalent in our society (Weiden et al., 1986).

Interventions to enhance compliance

A number of studies have evaluated the use of interventions to increase compliance. These include patient education (Gray 2000; Macpherson et al., 1996; Smith et al., 1992),

behavioural tailoring (Boczkowski et al., 1985) and compliance therapy (Kemp et al., 1996).

In a randomised controlled trial of education about drug treatment by Macpherson et al. (1996), 64 patients with DSM IIIR schizophrenia were randomly assigned to receive either:

- one session of education about medication;
- three sessions of education about medication; or
- Standard care.

The educational sessions were based on a specially designed booklet, drawn from psychoeducational literature and principles of health education. Sessions lasted between 25 and 35 minutes. Techniques included rehearsal of material with questions and feedback.

A range of measures were used, including the Knowledge about Medication Questionnaire (KMQ) a tool designed to gauge patients' knowledge of antipsychotic treatment. Patients were assessed at baseline, immediately post-intervention and at one-month follow-up. Pre-intervention, patients showed a poor understanding of their treatment. Both one and three sessions of education led to improvements in understanding about medication compared to standard care. However, three sessions led to significantly greater knowledge gain than one session.

Smith et al. (1992) and Gray (2000) also examined the effects of educational interventions on knowledge about medication, insight and attitudes towards treatment. Smith et al. (1992) divided their intervention into four sessions, each session designed to cover a different aspect of schizophrenia. Session 1 examined the concept of schizophrenia, including possible causes and outcome; Session 2 focused on the symptoms of schizophrenia; Session 3 emphasised the advantages, limitations, and side-effects of the treatment of schizophrenia; Session 4 outlined basic symptom management strategies. Twenty-eight patients participated in the study and significant gains in their knowledge of treatment were observed post intervention. However, no significant changes in insight or compliance with medication scores were reported.

Gray (2000) examined the effects of education about medication on patients who were taking clozapine. Forty-four patients were randomly assigned to receive either three sessions of education or standard care. As in the Smith et al. (1992) study, sessions focused on the concept, the symptoms and the treatment of schizophrenia. Patients' knowledge of the potential side effects of medication increased. However, no changes in patients' attitudes towards treatment or insight were reported.

Boczkowski et al. (1985) took a very different approach to trying to improve compliance. They assigned 36 male patients with chronic schizophrenia to receive one session of either behavioural tailoring, patient education or a control intervention. Behavioural tailoring involved informing patients of the importance of complying with their medication and helping the patient to tailor their prescribed regimen so that it was better

suited to their personal habits and routines. Compliance was measured via pill counts at three time points: pre-intervention, one-month follow-up and three-month follow-up. Results suggested that patients who received behavioural tailoring were more compliant following treatment than were the other groups.

In a seminal study, Kemp et al. (1996) evaluated the effectiveness of compliance therapy, a brief pragmatic intervention based on motivational interviewing and cognitive behavioural therapy which aims to help patients work through ambivalence about behaviour change. Key skills include the use of inductive questioning, reflective listening, use of summarising, investigating the pros and cons of alternative courses of action and homing in on and reinforcing adaptive attitudes and behaviours (Kemp et al., 1997). Compliance therapy is divided into three distinct phases: phase 1 is concerned with reviewing the patients' illness history, phase 2 explores ambivalence towards treatment and phase 3 highlights the need for treatment maintenance.

In a randomised controlled trial 47 patients were randomly assigned to receive 4-6 sessions lasting 10-60 minutes each, of either compliance therapy or non-specific counselling. Patients were assessed pre-intervention, post-intervention and at one, three, and six-month follow-up using measures of insight into illness, attitudes towards treatment and compliance. Patients who received compliance therapy showed significantly greater improvements in attitudes towards treatment insight and compliance, which were sustained at six-month follow-up.

The evidence suggest that an effective medication management intervention will include the careful assessment of patients' psychopathology, beliefs about treatment, insight, antipsychotic side effects, and other factors that may affect compliance. Is structured, educative and collaborative. The therapist and patient work together to explore and discuss concerns about treatment.

Overview of intervention and therapeutic techniques

Structure of sessions

Patients should ideally be seen individually, the duration and frequency of sessions will need to be defined by individual therapists depending on the patient's level of cognitive function. It is recommended that the intervention will initially involve approximately 10 hours individual work followed by ongoing top-up sessions. The aim of the medication management intervention is not only to help the patient examine the use of pharmacological interventions to treat their illness but also to provide them with the skills to help them manage their medication in the future.

Baseline assessment

This is the first stage of the intervention, normally lasts several sessions and involves the completion of formal clinical measures of:

- Psychopathology - using the PANSS (Kay et al., 1989)
- Beliefs about medication – using the Hogan drug attitude inventory (DAI-30, Hogan et al., 1983)

- Insight – using the Insight Scale for Psychosis (ISP, Birchwood et al., 1994)
- Side effects – using the LUNSERS (Day et al., 1995)

During this stage of the intervention the therapist helps the patient to identify specific problems and targets for treatment as well as engaging the patient in discussing their medication. Once these problems have been identified they should be listed and ranked by the patient. A clear treatment rationale, that the therapist wants to work collaboratively with the patient in addressing issues around medication, is presented. A formulation and plan of therapeutic tasks and homework is then discussed. Considerable time should be devoted to the careful assessment and review of the patients' medication as this will not only aid engagement but may also have some therapeutic benefit.

Structure of sessions and general therapeutic skills
The therapist should carefully plan and structure each session dependent on his or her level of functioning. At the beginning of each session the therapist must set a clear agenda with the patient with specific and relevant areas for discussion and set clear time limits. General therapeutic approaches that should be used include carefully eliciting and responding to verbal and non-verbal feedback; understanding the patients' views of medication and treatment; and encouraging the patient to take an active role during the sessions. Guided discovery is a central skill with the therapist helping the patient to explore problems and draw their *own* conclusions. These general therapeutic approaches form the foundation for the application of more specific medication management techniques.

Medication management and compliance therapy techniques

Providing information
Providing patients with information about their illness and treatment is a central part of the intervention and misconceptions and lack of understanding about any aspect of treatment should be clarified at any opportunity.

The illness timeline
Patients identify when they, or significant others, first realised they had psychiatric problems and then plot the course of their illness and the positive and negative effects of treatment over time. Close attention should be paid to helping the patient identify when their mental health has been particularly good and when it has been not so good. The purpose of this exercise is two-fold; firstly it helps the patient make any links between stopping medication and worsening psychopathology and secondly to identify and examine negative experiences of treatment, particularly where medication had been forcibly administered.

Normalising rationales
Drawing an illness timeline may be linked to the use of normalising rationales to explain both psychotic pathology and the need for maintenance treatment. A rationale should be discussed with the patient and the typical symptoms of, and possible genetic predisposition to, schizophrenia are then described. The vulnerability-stress model

(Zubin, 1987) should then be explained in detail, with the therapist making specific links to the work done in reviewing the illness timeline, to help the patient identify that their psychotic symptoms may be caused by an increased susceptible to stress. If the patient accepts this rationale then further work could be undertaken with the therapist helping the patient to draw analogies to other physical illnesses such as diabetes or asthma where maintenance treatment is necessary to prevent relapse.

Drawing up a balance sheet
Patients are helped to draw up a balance sheet to highlight both the positive and negative aspects of treatment. Emphasis should be placed on identifying the less obvious, or indirect, effects of medication (staying out of hospital, getting into fewer arguments, less problems with the neighbours). Dependent on the patients' level of functioning this activity may be done as homework with the therapist expanding and clarifying the work the patient had already undertaken.

Testing beliefs about illness and medication
Patients' beliefs about their illness and medication should be tested by using a modified version of the cognitive behavioural procedures for examining delusions (Chadwick *et al.*, 1996). Patients' beliefs about their illness and medication are identified from the drug attitude inventory and listed. The patient then rates the beliefs in terms of their influence on compliance. The beliefs are then rated on a percentage scale (0%=don't believe it at all, 100%=belief held with complete conviction). If the belief is held with less than 100% conviction it is gently challenged; the plausibility of the belief is questioned; and the belief is reformulated as being an understandable response to, and way of making sense of, specific experiences, and a personally meaningful alternative is constructed. Finally, the patients' belief and the alternative are assessed (using the percentage scale) in the light of the available information.

Specific problems with medication
Specific problems with medication, such as side effects, should be examined using a problem solving strategy (Hawton and Kirk, 1989). A problem is selected and a target is agreed. The broad steps necessary to achieve this goal are then identified and the patient decides, in detail, the practical and realistic tasks that would be necessary to achieve this goal. Progress is then reviewed in subsequent sessions

Examine the consequences of stopping medication
The Patients is asked to list the positive and negative aspects of stopping medication. Again this is a potential homework task dependent on the patients' level of functioning.

Long term plans
Patients are asked to look six to twelve months into the future and identify a goal they want to achieve. A problem solving strategy is utilised to identify broad and specific tasks needed to achieve this objective.

Medication review
The patients' medication is reviewed by the therapist and compared to the Bethlem and Maudsley Prescribing Guidelines. Any discrepancies e.g. antipsychotic polypharmacy, use of very high doses of antipsychotic or long term use of anticholinergics are discussed with the patient and the prescriber. Practical solutions to tackling side effects, identified by the patient as problematic, should be discussed at this time (for example, timing of administration, route of administration). The aim of medication review is to ensure that the patient is on the most effect treatment regime.

Behavioural tailoring
Much non-compliance may be accidental because patients simply forget to take medication. The therapist should identify how frequently this happens and simplify dosing regimes, use visual prompts to remind patients to take medication, and make use of doset boxes.

Re-assessments
Following the initial sessions with the patient the therapist should repeat the assessments. This will allow the therapist to evaluate, in clinical supervision, if the work they have been doing has been effective. It will also allow the therapist to identify areas where top up sessions can be targeted.

Supervision
You should discuss the medication management work with you supervisor on a regular basis. You will also have the opportunity to present one patient you are working with as part of the medication management course. You can also get online supervision by emailing specific questions to R.Gray@iop.kcl.ac.uk or by telephoning Richard Gray on 020 7848 0139.

References/reading list

Angermeyer, M. C. and Matschinger, H. (1994) Lay beliefs about schizophrenic disorder: the results of a population survey in Germany. Lubeck symposium: The role of compliance in the treatment of schizophrenia. *Acta Psychiatric Scandinavica,* 89 (supplement 382), 39-45.

Applebaum, P. S. and Gutheil, T. G. (1980) Drug refusal: a study of psychiatric inpatients. *American journal of Psychiatry,* 137, 340-346.

Babiker, I. E. (1986) Noncompliance in schizophrenia. *Psychiatric Developments.* 4, 329-337.

Bartko, G. *et al.*, (1988) Clinical symptomatology and drug compliance in schizophrenic patients. *Acta Psychiatrica Scandinavica.* 77, 74-76.

Birchwood M., *et al.* (1994) A self-report insight scale for psychosis: reliability, validity and sensitivity to change. *Acta Psychiatrica Scandinavica,* 89, 62-67.

Bocczowski, J. A. *et al.* (1985) Neuroleptic compliance among chronic schizophrenic outpatients: an intervention outcome report. *Journal of Consulting and Clinical Psychology.* 53, 666-671.

Buchanan, A. (1992) A two-year prospective study of treatment compliance in patients with schizophrenia. *Psychological medicine,* 22, 787-797.

Day, J. *et al.* (1995) A self-rating scale for measuring neuroleptic side-effects: validation in a group of schizophrenic patients. *British Journal of Psychiatry,* 166, 650-653.

Geller, L. J. (1982) State hospital patients and their medication: do they know what they take? *American Journal of Psychiatry,* 139, 5, 611-615.

Gray, R. (2000) Does patient education enhance compliance with clozapine? A preliminary investigation. *Journal of Psychiatric and Mental Health Nursing.*

Green, J. H. (1988) Frequent rehospitilisation and non-compliance with treatment. *Hospital and Community Psychiatry,* 39, 963-966.

Hayward, P., *et al.* (1995) Medication self-management: a preliminary report on an intervention to improve medication compliance. *Journal of Mental Health,* 4, 5, 511-519.

Hogan, T. P. and Awad, A. G. (1983) Subjective response to neuroleptics and outcome in schizophrenia: a re-examination comparing two measures. *Psychological medicine,* 22, 347-352.

Hoge, S. K. *et al.* (1990) A prospective, multi-centre study of patients' refusal of antipsychotic medication. *Archives of General Psychiatry,* 47, 10, -949-956.

Kay *et al* (1989) *Positive and Negative Syndrome Scale. PANSS x/- Manual.* Multi-Health Systems, Inc. New York.

Kemp R. and David A. (1995) Insight and adherence to treatment in psychotic disorders. *British journal of Hospital Medicine.* 54, 222-227.

Kemp R. *et al* (1996) Compliance therapy in psychotic patients: a randomised controlled trial. *British Medical Journal.* 312, 345-349.

Kemp R. *et al.* (1997) *Compliance therapy manual.* Bethlem and Maudsley NHS Trust, London.

Kissling, W. (1994) Compliance, quality assurance and standards for relapse prevention in schizophrenia. *Acta Psychiatrica Scandinavica.*89, (supplement 382), 16-24.

Lin, H. F. *et al.* (1979) Insight and adherence to medication in chronic schizophrenics. *Journal of Consulting and Clinical Psychiatry,* 40, 430-432.

McEvoy, J. P. *et al* (1989) insight and the clinical outcome of schizophrenic patients. *Journal of nervous and Mental Disorders.* 177, 1, 48-51.
Macpherson, R. *et al.* (1996) a controlled study of education and drug treatment in schizophrenia. *British Journal of Psychiatry,* 168, 709-717.
Marder S. R. *et al* (1983) A comparison of patients who refuse and consent to neuroleptic treatment. *American Journal of Psychiatry,* 140, 4, 470-472.
Michaux, W. W. (1961) Side effects, resistance and dosage deviations in psychiatric outpatients treated with tranquillisers. *Journa of Nervous and Mental Disease.* 133, 203-212.
Nelson, A. (1975) Drug default among schizophrenic patients. *American Journal of Hospital Pharmacy.* 32, 1237-1242.
Smith, J. *et al.* (1992) Informing people with schizophjrenia about their illness: the effect of residual symptoms. *Journal of Mental Health.* 1, 61-70.
van Putten T. (1974) Why do schizophrenic patients refuse to take their drugs? *Archives of general Psychiatry.* 31, 67-72.
van Putten, T. *et al.* (1976) Drug refusal in schizophrenia and the wish to be crazy. *Archives of General Psychiatry,* 33, 1443-1446.
van Putten, T. *et al.* (1981) Subjective response to antipsychotic drugs. *Archives of Genral Psychiatry.* 38, 187-190.
Weiden, P. J. *et al.* (1986) Causes of neuroleptic non-compliance. *Psychiatric Annals.* 16, 571-575.

Clinical supervision guidelines

You have one hour to present a patient that you have been working with. You are advised to spend the first 20 minutes presenting the patient using the framework below. You MUST end your presentation with a supervision question. You should then spend 30 minutes discussing your supervision with the group and the final ten minutes deciding on an action plan. At the follow-up day you will need say what the outcome of your action plan was.

Structure of presentation

- Psychiatric history
- Medication history
- Compliance strategies used in the past
- Assessment
  Psychopathology (using the PANSS)
  Attitudes towards treatment (using the DAI-30)
  Insight (using the ISP)
  Side effects (using the LUNSERS)
- Patient formulation
- Problems and targets
- Supervision question

Summary of discussion

Action plan

Day two

Agenda

9:30 Signs and symptoms of schizophrenia

11:00 Aetiology of schizophrenia

1:00 Assessing symptoms (video rating)

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

Homework

It is essential that before next weeks session that you read the following:

Gray R. and Smedley N. (1997) Nursing Interventions with acutely ill clients. In: Thomas B. *et al.,* (Eds) *Stuart and Sundeen's Mental Health Nursing.* Mosby, London.

The Structure Clinical Interview (SCI)

Both are in your background reading pack.

Signs and symptoms

Schizophrenia

- Clinical presentation varies
  - Between individual
  - Within individuals

Hallucinations

- Auditory
- Visual
- Tactile
- Olfactory
- Gustatory
- Bizarre sensations in body organs

Delusions

- Paranoid
  - Persecutory
  - Delusions of reference
- Somatic
- Religious
- Nihilistic
- Grandiose

Thought disorder

- Formal though disorder
  - Loosening of associations
  - Poverty of content of speech
  - Thought block
  - Neologisms

Passivity phenomena

- Thought broadcasting
- Thought insertion
- Thought withdrawal
- Made feelings
- Made actions

Abnormal affect

- Blunt of flat
- Inappropriate or incongruous
- Response to delusions or voices common

Cognitive deficits

- Normally orientated
- Attention
- Concentration
- Memory and learning

Motor abnormalities

- Posturing
- Waxy flexibility
- Negativism
- Echopraxia
- Sterotypy
- Catatonic excitement
- Catatonic stupor

Lack of volition

- Lack of drive
- Diminished interest in the outside world
- Common in chronic stages of illness

Lack of insight

- Very common
- Associated with non-compliance

Clinical phases

- Premorbid phase
  - Social and cognitive deficits traced to childhood
- Prodromal
  - Emergence of actual functional decline
- Insidious and gradual

Course

- Used to considered one of continuos deterioration
- Seems to be a great degree of variability
- Course established within the first five years

Outcome

- Symptomatic recovery
- Level of social functioning

Factors associated with a good outcome

- Female
- Married
- No previous psychiatric history
- Good social relationship
- Acute onset
- Older age
- Florid symptoms

Outcome of schizophrenia

- Lifespan shortened by 10 years
- 10% commit suicide
- Accidents
- Cardiovascular disease

Epidemiology

- Occurs in all cultures
- Incidence 2-4 cases per 10,000 of the population per year
- Lifetime risk 1%

Temporal variation

- Increased incidence in 19th Century
- May be declining

Social factors

- Schizophrenia more common in industrialised countries
- More schizophrenic patients in lower socioeconomic classes
- Admission rates higher in urban than rural areas

Immigration

- Higher incidence in recent immigrants
- Stress of leaving home country
- Not because of cultural intolerance

Fertility and seasonality of birth

- Fertility rates reduced by 25%
- Northern hemisphere more people with schizophrenia (8%) born between January and April
- Reversed in southern hemisphere

Aetiology of schizophrenia

Exercise one

List what you think are the causes of schizophrenia

Aetiology

- Biological
- Environmental

Genetics

- Family studies
- Adoption studies
  - Adoptee studies
  - Adoptee family studies
  - Cross fostering studies
- Twin studies
- Molecular genetic studies

Genetics

- Schizophrenia does not follow a Mendelian pattern
- Models
  - Single locus of inheritance
  - Polygenic/multifactorial
  - Hetrogeneity

Pregnancy and birth complications

- More PBCs in patients with schizophrenia
- Hypoxic/ischemic neuronal injury
- Cause or effect

Prenatal exposure to viral infection

- More schizophrenics born in late winter and spring
- Exposure to influenza epidemics during second trimester
- Remains controversial

Richard Gray, Institute of Psychiatry, London

Family interactions

- Brown (1959)
- Expressed emotion
- EE a robust predictor of relapse
- Low EE protective
- EE has any effect in other disorders

Richard Gray Institute of Psychiatry, London

Life events

- More life events than normal controls prior to relapse
- Cause or effect

Richard Gray, Institute of Psychiatry, London

POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

Exercise
You will be shown a video of a patient being interviewed by a clinician who is experienced in using the structured clinical interview (SCI). The video lasts 30-40 minutes. Watch the video carefully making notes of the psychopathology that you observe. Once the video has finished complete the rating criteria below using the rating criteria in your reading pack. REMEMBER you only rate what has been observed or reported in the last seven days. REMEMBER you are looking for evidence. Once you have completed the rating you will be asked to feedback to the group. If your score is substantially different form the other members of the group you will be asked to justify (with evidence) what you have rated.

POSITIVE SUBSCALE
____ P1 Delusions
____ P2 Conceptual disorganisation
____ P3 Hallucinatory behaviour
____ P4 Excitement
____ P5 Grandiosity
____ P6 Suspiciousness/persecution
____ P7 Hostility

NEGATIVE SUBSCALE
____ N1 Blunted affect
____ N2 Emotional withdrawal
____ N3 Poor rapport
____ N4 Passive/apathetic social withdrawal
____ N5 Difficulty in abstract thinking
____ N6 Lack of spontaneity and flow of conversation
____ N7 Stereotyped thinking

GENERAL PSYCHOAPTHOLOGY
____ G1 Somatic concern
____ G2 Anxiety
____ G3 Guilt feeling
____ G4 Tension
____ G5 Mannerism and posturing
____ G6 Depression
____ G7 Motor retardation
____ G8 Uncooperativeness
____ G9 Unusual thought content
____ G10 Disorientation
____ G11 Poor attention
____ G12 Lack of judgement and insight
____ G13 Disturbance of volition
____ G14 Poor impulse control
____ G15 Preoccupation
____ G16 Active social avoidance

Severity rating key
1=Absent
2=Minimal
3=Mild
4=Moderate
5=Moderately severe
6= Severe
7=Extreme

Day three

Agenda

Agenda

9:30 Assessing symptoms (video rating)

2:00 Role play of structured clinical interview (SCI)

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

Homework
By next weeks session you should have interviewed one patient using the structured clinical interview and completed one PANSS rating. It is advisable that the patient you interview should be the patient you present for clinical supervision.

POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

Exercise
You will be shown another video of a patient being interviewed by a clinician who is experienced in using the structured clinical interview (SCI). The video lasts 30-40 minutes. Watch the video carefully making notes of the psychopathology that you observe. Once the video has finished complete the rating criteria below using the rating criteria in your reading pack. REMEMBER you only rate what has been observed or reported in the last seven days. REMEMBER you are looking for evidence. Once you have completed the rating you will be asked to feedback to the group. If your score is substantially different form the other members of the group you will be asked to justify (with evidence) what you have rated.

POSITIVE SUBSCALE
____ P1 Delusions
____ P2 Conceptual disorganisation
____ P3 Hallucinatory behaviour
____ P4 Excitement
____ P5 Grandiosity
____ P6 Suspiciousness/persecution
____ P7 Hostility

NEGATIVE SUBSCALE
____ N1 Blunted affect
____ N2 Emotional withdrawal
____ N3 Poor rapport
____ N4 Passive/apathetic social withdrawal
____ N5 Difficulty in abstract thinking
____ N6 Lack of spontaneity and flow of conversation
____ N7 Stereotyped thinking

GENERAL PSYCHOAPTHOLOGY
____ G1 Somatic concern
____ G2 Anxiety
____ G3 Guilt feeling
____ G4 Tension
____ G5 Mannerism and posturing
____ G6 Depression
____ G7 Motor retardation
____ G8 Uncooperativeness
____ G9 Unusual thought content
____ G10 Disorientation
____ G11 Poor attention
____ G12 Lack of judgement and insight
____ G13 Disturbance of volition
____ G14 Poor impulse control
____ G15 Preoccupation
____ G16 Active social avoidance

Severity rating key
1=Absent
2=Minimal
3=Mild
4=Moderate
5=Moderately severe
6= Severe
7=Extreme.

Exercise

Divide into pairs, one person should be a patient and the other interviewer. The person who is going to role-play the patient should try to be a client that they know well (this should make them more convincing). The interviewer should then conduct the structured clinical interview. Think carefully about how the interview is presented to the patient and how you will inform them of what you have found out about their experiences. REMEMBER the aim of the exercise is to familiarise yourself with the interview.

When you have finished the patient should give the interviewer feedback about what they did well and what they could have done differently.

Now reverse the roles so that the person that was the interviewer is the patient and the person that was the patient is the interviewer.

Day four

Agenda

9:30 Assessing side effects

11:00 Assessing patients' beliefs about medication

1:00 Assessing insight

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

Homework

You must assess one patient using the self-report measures you have learnt to use. Again this should be the patient you will present for you clinical supervision presentation.

Liverpool University Neuroleptic Side Effect Rating Scale

LUNSERS

The following pages are a copy of the LUNSERS which is fully a validated and reliable means of assessing neuroleptic side effects. It includes 41 known side effects of neuroleptics and 10 "red herring" items such as 'hair loss' and 'chilblains' that are not known side effects of neuroleptic medication. The red herring items are numbers 3, 8, 11, 12, 25, 28, 30, 33, 42 and 45. These should be scored separately as this score may indicate individuals who overscore generally on the scale (a high score would be over 20 for example). The scoring is as follow:

Not at all	= 0
Very little	= 1
A little	= 2
Quite a lot	= 3
Very much	= 4

The real neuroleptic side effect score is the sum for the remaining items (all items excluding the red herrings).

LUNSERS

Assessment date ☐☐☐☐☐☐ Assessment no. ☐

Please indicate how much you have experienced each of the following symptoms in **the last month** by ticking the appropriate boxes.

		Not at all	Very little	A little	Quite a lot	Very much
1.	Rash	☐	☐	☐	☐	☐
2.	Difficulty staying awake during the day	☐	☐	☐	☐	☐
3.	Runny nose	☐	☐	☐	☐	☐
4.	Increased dreaming	☐	☐	☐	☐	☐
5.	Headaches	☐	☐	☐	☐	☐
6.	Dry mouth	☐	☐	☐	☐	☐
7.	Swollen or tender chest	☐	☐	☐	☐	☐
8.	Chillblains	☐	☐	☐	☐	☐
9.	Difficulty in concentrating	☐	☐	☐	☐	☐
10.	Constipation	☐	☐	☐	☐	☐
11.	Hair loss	☐	☐	☐	☐	☐
12.	Urine darker than usual	☐	☐	☐	☐	☐

		Not at all	Very little	A little	Quite a lot	Very much
13.	Period problems	☐	☐	☐	☐	☐
14.	Tension	☐	☐	☐	☐	☐
15.	Dizziness	☐	☐	☐	☐	☐
16.	Feeling sick	☐	☐	☐	☐	☐
17.	Increased sex drive	☐	☐	☐	☐	☐
18.	Tiredness	☐	☐	☐	☐	☐
19.	Muscle stiffness	☐	☐	☐	☐	☐
20.	Palpitations	☐	☐	☐	☐	☐
21.	Difficulty in remembering things	☐	☐	☐	☐	☐
22.	Losing weight	☐	☐	☐	☐	☐
23.	Lack of emotions	☐	☐	☐	☐	☐
24.	Difficulty achieving climax	☐	☐	☐	☐	☐
25.	Weak fingernails	☐	☐	☐	☐	☐
26.	Depression	☐	☐	☐	☐	☐
27.	Increased sweating	☐	☐	☐	☐	☐

		Not at all	Very little	A little	Quite a lot	Very much
28.	Mouth ulcers	☐	☐	☐	☐	☐
29.	Slowing of movements	☐	☐	☐	☐	☐
30.	Greasy skin	☐	☐	☐	☐	☐
31.	Sleeping too much	☐	☐	☐	☐	☐
32.	Difficulty passing water	☐	☐	☐	☐	☐
33.	Flushing of face	☐	☐	☐	☐	☐
34.	Muscle spasms	☐	☐	☐	☐	☐
35.	Sensitivity to sun	☐	☐	☐	☐	☐
36.	Diarrhoea	☐	☐	☐	☐	☐
37.	Over-wet or drooling mouth	☐	☐	☐	☐	☐
38.	Blurred vision	☐	☐	☐	☐	☐
39.	Putting on weight	☐	☐	☐	☐	☐
40.	Restlessness	☐	☐	☐	☐	☐
41.	Difficulty getting to sleep	☐	☐	☐	☐	☐
42.	Neck muscles aching	☐	☐	☐	☐	☐

		Not at all	Very little	A little	Quite a lot	Very much
43.	Shakiness	☐	☐	☐	☐	☐
44.	Pins and needles	☐	☐	☐	☐	☐
45.	Painful joints	☐	☐	☐	☐	☐
46.	Reduced sex drive	☐	☐	☐	☐	☐
47.	New or unusual skin marks	☐	☐	☐	☐	☐
48.	Parts of body moving on their own	☐	☐	☐	☐	☐
49.	Itchy skin	☐	☐	☐	☐	☐
50.	Periods less frequent	☐	☐	☐	☐	☐
51.	Passing a lot of water	☐	☐	☐	☐	☐

LUNSERS

Side-effects by group

Extrapyramidal side effects 19 Muscle stiffness 29 Slowing of movements 34 Muscle spasms 40 Restiessness 43 Shakiness 48 Parts of the body moving on their own 37 Over-wet or drooling mouth **Possible range 0 – 28**	**Anticholinergic side effects** 6. Dry mouth 10. Constipation 32. Difficulty passing water 38. Blurred vision 51. Passing a lot of water **Possible range 0-20**
Other autonomic 15. Dizziness 16. Feeling sick 20. Palpitations 27. Increased sweating 36. Diarrhoea **Possible range 0 – 20**	Allergic reactions 1. Rash 35. Sensitivity to sun 47. New or unusual skin marks 49. Itchy skin **Possible range 0 - 16**
Psychic side effects 2. Difficulty staying awake during the day 4 . Increased dreaming 9. Difficulty in concentrating 14. Tension 18. Tiredness 21. Difficulty in remembering things 23. Lack of emotions 26. Depression 31. Sleeping too much 41. Difficulty getting to sleep **Possible range 0 – 40**	Hormonal side effects 7. Swollen or tender chest 13. Period problems - women only 17. Increased sex drive 24. Difficulty in achieving climax 46. Reduced sex drive 50. Periods less frequent - women only **Possible range Women 0 - 24, Men 0 – 16**
Miscellaneous 5. Headaches 22. Losing weight 39. Putting on weight 44. Pins and needles **Possible range 0- 16**	Red Herrings 3. Runny nose 8. Chilblains 11. Hair loss 12. Urine darker than usual 25. Weak finger nails 28. Mouth ulcers 30. Greasy skin 33. Flushing of face 42. Neck muscles aching 45. Painful joints **Possible range 0 – 40**

Possible range for total scores

LUNSERS side effect scores only	LUNSERS all 51 items
Women 0-164	Women 0-204
Men 0-156	Men 0-196

Hogan Drug Attitude Inventory

Assessment date | | | | | | | Assessment no. | |

The purpose of this questionnaire is to gain some understanding of how people view the use of psychiatric medications and the nature of their experiences of these drugs. Your replies are used for research purposes only, are strictly confidential, and will in no way affect your treatment.

Please read each of the following statements and decide whether it is **true as applied to you** or **false as applied to you.** If the statement is **false** or **usually false,** circle the **F** following the statement. If the statement is **true** or **usually true,** circle the **T** following the statement. If you want to change an answer, mark an **X** over the incorrect answer and circle the correct answer.

Please answer every question. If a statement is worded not quite the way you would express it yourself, decide whether it is **mostly true** or **mostly false.** Remember to give your own opinion- there are no right or wrong answers. Do not spend too much time on any one item.

The medications referred to in the statements are psychiatric medications only.

1. I don't need to take medication once I feel better. **T F**
2. For me, the good things about medication outweigh the bad. **T F**
3. I feel weird, like a 'zombie', on medication. **T F**
4. Even when I am not in hospital I need medication regularly. **T F**
5. If I take medication it's only because of pressure from other people. **T F**
6. I am more aware of what I am doing, of what is going on around me, when I am on medication. **T F**
7. Taking medications will do me no harm. **T F**
8. I take medications of my own free choice. **T F**
9. Medications make me feel more relaxed. **T F**
10. I am no different on or off medication. **T F**
11. The unpleasant effects of medication are always present. **T F**
12. Medication makes me feel tired and sluggish. **T F**
13. I take medication only when I am sick. **T F**
14. Medication is a slow-acting poison. **T F**
15. I get on better with people when I am on medication. **T F**

16. I can't concentrate on anything when I am on medication. **T F**

17. I know better than the doctor when to go off medication. **T F**

18. I feel more normal on medication. **T F**

19. I would rather be sick than taking medication. **T F**

20. It is unnatural for my mind and body to be controlled by medication. **T F**

21. My thoughts are clearer on medication. **T F**

22. I should stay on medication even if I feel all right. **T F**

23. Taking medication will prevent me from having a breakdown. **T F**

24. It is up to the doctor when I go off medication. **T F**

25. Things that I could do easily are much more difficult when I am on medication. **T F**

26. I am happier, feel better, when taking medication. **T F**

27. I am given medication to control behaviour that other people (not myself) don't like. **T F**

28. I can't relax on medication. **T F**

29. I am in better control of myself when taking medications. **T F**

30. By staying on medications I can prevent getting sick. **T F**

If you have any further comments about medications or about this questionnaire, please write them below.

Please do not write below this line

SCORING CRITERIA

The scale has 15 items that will be scored as **True** and 15 items that will be scored as **False** in the case of a fully compliant response. A correct answer to these items will be scored as plus 1. An incorrect answer will be scored as minus 1. The total score is the sum of pluses and minuses. A positive total score means a compliant response. A negative total score means a non-compliant response.

Below is the standard of a completely compliant response profile.

1.	F	11.	F	21.	T
2.	T	12.	F	22.	T
3.	F	13.	F	23	T
4.	T	14.	F	24.	T
5.	F	15.	T	25.	F
6.	T	16.	F	26.	T
7.	T	17.	F	27.	F
8.	T	18.	T	28.	F
9.	T	19.	F	29.	T
10.	F	20.	F	30.	T

Insight scale for psychosis (ISP)

Assessment date ☐☐☐☐☐☐ Assessment no. ☐

Please read the following statements carefully and then tick the box which ***best*** applies to you

		Agree	Disagree	Unsure
1.	Some of my symptoms are made by my mind	☐	☐	☐
2.	I am mentally well	☐	☐	☐
3.	I do not need medication	☐	☐	☐
4.	My stay in hospital is necessary	☐	☐	☐
5.	The doctor is right in prescribing medication for me	☐	☐	☐
6.	I do not need to be seen by a doctor or psychiatrist	☐	☐	☐
7.	If someone said I have a nervous or a mental illness they would be right	☐	☐	☐
8.	None of the unusual things I experience are due to an illness	☐	☐	☐

ISP scoring criteria

		Agree	Disagree	Unsure
1.	Some of my symptoms are made by my mind	2	0	1
2.	I am mentally well	0	2	1
3.	I do not need medication	0	2	1
4.	My stay in hospital is necessary	2	0	1
5.	The doctor is right in prescribing medication for me	2	0	1
6.	I do not need to be seen by a doctor or psychiatrist	0	2	1
7.	If someone said I have a nervous or a mental illness they would be right	2	0	1
8.	None of the unusual things I experience are due to an illness	0	2	1

Items
1+8 = Relable (total 4)
2+7 = Awareness of illness (total 4)
3+4+5+6/2 =Need for treatment (total 4)

EXERCISE

In pairs (one person the therapist, one the patient) complete the self-report measures (if necessary working through the measures with the patient). Think carefully about how you present the assessments. Once they have been completed score them and try to work out, with the patient, particular problems they have with medication e.g. specific side effects, don't believe they need it, think that it is poison (patient formulation/problems and targets). Think about the interventions that you would use to address these problems. When you have completed the exercise reverse roles and repeat.

Patient formulation

Problems and targets

Day five

9:30 Clinical supervision

11:30 Psychopharmacology

1:00 Key skills in medication management (reviewing the patients' illness history)

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

Homework

You must read:
Taylor D. and Thomas B (1997) Psychopharmacology. In Thomas B. (ed) *Stuart and Sundeens Mental Health Nursing*. Mosby, London

Kemp, R. Hayward P. and David A. (1997) *The compliance therapy manual.* The Bethlem and Maudsey NHS Trust.

These papers/manuals are in your reading pack.

You should familiarise yourself with:
Taylor D. McConnell D. McConnell H. (1999) *The Bethlem and Maudsley NHS Trust Prescribing Guidelines 5th Edition.* Martin Dunitz, London.

Psychopharmacology

Schizophrenia

- Most serious of mental disorder
- Prevalence - approximately 1%

Schizophrenia

- Positive symptoms e.g. hallucinations, delusions, thought disorder
- Negative symptoms e.g. lack of motivation, social withdrawal, emotional blunting

Dopamine hypothesis

- Increased dopaminergic neurotransmission is a pathogenic factor of schizophrenia

Dopamine hypothesis

- Evidence for
  - All antipsychotics block post-synaptic D_2-receptors
  - PM - increase D_2 - receptors

Dopamine hypothesis

- Evidence against
  - In vivo scans shown no difference in D_2 receptor density
  - 20-30% treatment refractory

Dopamine D_2 blockade

- Cortex
  - Antipsychotic effect

Dopamine D_2 blockade

- Striatum
  - Extrapyramidal symptoms
    - Parkinsonism
    - dystonia
    - akathisia
  - Risk factor for tardive dyskinesia

Dopamine D_2 blockade

- Hypothalamus
  - Hyperprolactinemia
    - amenorreoa
    - galactorrheoa
    - gynaecomastia
    - sexual dysfunction

Typical antipsychotics

- Efficacy vs. positive symptos
- Residual symptoms ++++
- EPS
- TD
- Hyperprolactinemia
- Others

Predictable adverse effects

- Hypotension, dizziness, sedation
- EPS, hyperprolactinaemia, TD, NMS
- Sedation
- Dry mouth, blurred vision, urinary retention, constipation, confusion

Unpredictable adverse effects

- Ocular deposits
- Photosensitivity
- Hepatitis
- ECG changes
- Convulsions
- Blood dyscrasias

Adverse effects

- Use of typical antipsychotics limited by adverse effects
- EPS
- Can be used to their advantage e.g. chlorpromazine

Introduction of atypical drugs

- Clozapine 1990
- Risperidone 1993
- Sertindole 1996
- Olanzapine 1996
- Quetiapine 1997
- Amisulpiride 1997
- Zotepine 1998

Atypical antipsychotics

- Atypical implies EPS sparing
- Lower propensity for EPS/no propensity for EPS
- Does not necessarily mean better efficacy

Extrapyramidal symptoms

- Haloperidol +++
- Clozapine 0
- Risperidone +
- Sertindole 0
- Olanzapine 0
- Quetiapine 0
- Zotepine +

Tardive dyskinesia

- Typical drugs - incidence 5% per year
- Clozapine improves symptoms
- Olanzapine - incidence 1% per year
- No evidence for other atypicals

Neuroleptic malignant syndrome

- Rare - potentially fatal
- Difficult to diagnose
- Reports with atypical
- Symptoms
  - ⇑ temperature
  - labile b.p.
  - muscle rigidity
  - altered consciousness
  - ⇑ creatinine kinase

Hyperprolactinaemia

- Haloperidol +++
- Clozapine 0
- Risperidone ++
- Sertindole 0
- Olanzapine +
- Quetiapine 0
- Zotepine +

Weight gain

- Haloperidol +
- Clozapine +++
- Risperidone +
- Sertindole ++
- Olanzapine +++
- Quetiapine ++

Antipsychotic efficacy in positive symptoms

- Clozapine superior for positive and negative symptoms in non-refractory and refractory schizophrenia
- All other antipsychotics - equal efficacy

Antipsychotic efficacy in negative symptoms

- Equal efficacy for typical drugs
- Atypical have superior efficacy to typical, but differences between them
  - Clozapine +++
  - Risperidone +
  - Sertindole (16mg)
  - Olanzapine ++
  - Quetiapine ?

Antipsychotic efficacy in refractory schizophrenia

- *Clozapine - good evidence*
- Risperidone - weak evidence
- Olanzapine - weak evidence

Choosing an antipsychotic

Balance between efficacy and tolerability

Drug interactions

- Pharmacodynamic
  - Two drugs acting on the same physiological systems
  - Predict from pharmacology
  - Antimuscarinic, sedative, hypotensive effects

Drug interactions

- Pharmacokinetic
  - Alteration of
    - absorption
    - distribution
    - metabolism
    - excretion

Metabolism

- Inhibition or induction
  - CYP2D6
  - CYP3A4
  - CYP1A2

Key skills in medication management

The illness timeline
Patients identify when they, or significant others, first realised they had psychiatric problems and then plot the course of their illness and the positive and negative effects of treatment over time. Close attention should be paid to helping the patient identify when their mental health has been particularly good and when it has been not so good. The purpose of this exercise is two-fold; firstly it helps the patient make any links between stopping medication and worsening psychopathology, and secondly to identify and examine negative experiences of treatment, particularly where medication had been forcibly administered.

Time:	5 minutes
Skills to be rated:	Agenda setting, interpersonal effectiveness, guided discovery, feedback
Agenda items:	Reviewing the patients' experience of treatment
Current medication:	Sulpiride
Patient:	You are 27 years old and have been taking antipsychotic medication for the last five years. You do not believe that you have a mental illness but you do acknowledge that you get "stressed out". Medication helps reduce the voices you hear but you stop taking it as soon as you leave hospital because you don't like the idea of taking it and are worried that you might be on it for life. You get some side effects which you find distressing. You are happy to talk to the therapist.

Day six

Agenda

9:30 Clinical supervision

11:30 Psychopharmacology

2:00 Key skills in medication management (exploring ambivalence)

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

Homework

You must read:

Gournay K. Gray R. Taylor D. (1997) New Drug treatments for schizophrenia. *Mental Health Nursing 4,55-59.*

Gray R. (in press) Effective dosing in the use of antipsychotics for the treatment of acute schizophrenia. *Mental Health Care*

These papers are in your reading pack

Key skills in medication management

Drawing up a balance sheet
Patients are helped to draw up a balance sheet to highlight both the positive and negative aspects of treatment. Emphasis should be placed on identifying the less obvious, or indirect, effects of medication (staying out of hospital, getting into fewer arguments, less problems with the neighbours). Dependent on the patients' level of functioning this activity may be done as homework with the therapist expanding and clarifying the work the patient had already undertaken.

Time:	5 minutes
Skills to be rated:	Agenda setting, interpersonal effectiveness, guided discovery, feedback, pacing
Agenda items:	Looking and the not so good and the good things about medication
Current medication:	Sulpiride
Patient:	You are 27 years old and have been taking antipsychotic medication for the last five years. You do not believe that you have a mental illness but you do acknowledge that you get "stressed out". Medication helps reduce the voices you hear but you stop taking it as soon as you leave hospital because you don't like the idea of taking it and are worried that you might be on it for life. You get some side effects which you find distressing. This is the second session with the interviewer with whom you are happy to talk. In the first session the interviewer helped you identify a pattern between stopping medication and relapse.

Day seven

Agenda

9:30 Clinical supervision

11:30 Psychopharmacology

2:00 Key skills in medication management (testing patient's beliefs about treatment)

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

Homework

Gray R. (1997) The administration of PRN medication by mental health nurses. *Journal of Psychiatric and Mental Health Nursing,* 4, 55-57.

Gray R. (in press) Antipsychotics, side effects and effective management. *Mental Health Practice.*

Both of these papers are in your reading pack.

Key skills in medication management

Testing beliefs about illness and medication

Patients' beliefs about their illness and medication should be tested by using a modified version of the cognitive behavioural procedures for examining delusions (Chadwick *et al.*, 1996). Patients' beliefs about their illness and medication are identified from the drug attitude inventory and listed. The patient then rates the beliefs in terms of their influence on compliance. The beliefs are then rated on a percentage scale (0%=don't believe it at all 100%=belief held with complete conviction). If the belief is held with less than 100% conviction it is gently challenged; the plausibility of the belief is questioned; and the belief is reformulated as being an understandable response to, and way of making sense of, specific experiences, and a personally meaningful alternative is constructed. Finally, the patients' belief and the alternative are assessed (using the percentage scale) in the light of the available information.

Time:	5 minutes
Skills to be rated:	Guided discovery, interpersonal effectiveness
Agenda items:	Look at beliefs about medication
Current medication:	Sulpiride
Patient:	You are 27 years old and have been taking antipsychotic medication for the last five years. You do not believe that you have a mental illness but you do acknowledge that you get "stressed out". Medication helps reduce the voices you hear but you stop taking it as soon as you leave hospital because you don't like the idea of taking it and are worried that you might be on it for life. You get some side effects which you find distressing. This is your third session with the interviewer, with whom you are happy to talk. In the first session the interviewer helped you identify a pattern between stopping medication and relapse. In the second you explored the not so good and the good things about medication.

Day eight

Agenda

9:30 Clinical supervision

11:30 User experiences

2:00 Key skills in medication management role play (problem solving)

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

Key skills in medication management

Specific problems with medication
Specific problems with medication, such as side effects, should be examined using a problem solving strategy (Hawton and Kirk, 1989). A problem is selected and a target is agreed. The broad steps necessary to achieve this goal are then identified and the patient decides, in detail, the practical and realistic tasks that would be necessary to achieve this goal. Progress is then reviewed in subsequent sessions

Time:	5 minutes
Skills to be rated:	Agenda setting, strategy for change
Agenda items:	Sorting out the side effects of medication
Current medication:	Sulpiride
Patient:	You are 27 years old and have been taking antipsychotic medication for the last five years. You do not believe that you have a mental illness but you do acknowledge that you get "stressed out". Medication helps reduce the voices you hear but you stop taking it as soon as you leave hospital because you don't like the idea of taking it. This is the forth session with the interviewer with whom you are happy to talk. You think that medication might be helpful but are concerned about the side effects that you get (sexual dysfunction, tremor, weight gain).

Day nine

Agenda

9:30 Clinical supervision

11:30 Dual diagnosis

2:00 Key skills in medication management (planning for the future)

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

Key skills in medication management

Long term plans
Patients are asked to look six to twelve months into the future and identify a goal the they want to achieve. A problem solving strategy is utilised to identify broad and specific tasks needed to achieve this objective.

Time:	5 minutes
Skills to be rated:	Strategy for change
Agenda items:	Planning for the future
Current medication:	Sulpiride
Patient:	You are 27 years old and have been taking antipsychotic medication for the last five years. You do not believe that you have a mental illness but you do acknowledge that you get "stressed out". Medication helps reduce the voices you hear but you stop taking it as soon as you leave hospital because you don't like the idea of taking it. This is the fifth session with the interviewer whom you are happy to talk to. You think that medication might be helpful but are concerned about taking it long term.

Day ten (follow-up day)

Agenda

SUBMISSION OF COURSE WORK

9:30 Clinical supervision updates

12:00 Course evaluation form

2:00 Multiple choice questionnaire

2:30 Video role-play

What is your personal aim for the day?

Aim: _____

_____

_____

Evaluation (include whether your aim was achieved): _____

_____

_____

COGNITIVE THERAPY SCALE

(Vallis et al.., 1986)

Therapist: _____

Date of session: _____

Tape ID Number: _____

Rater: _____

Date of Rating: _____

What was rated: 1. Video role-play ☐ 2. Live session ☐ 3. Audio tape ☐

Directions:	For each item, assess the therapist on a scale from 0 to 6, and record the rating in the space provided. Descriptions are given for even-numbered scale points. *If you believe the therapist falls between two of the descriptions, select the intervening odd number (1, 3, 5).* For example, if the therapist sets a very good agenda but did not establish priorities, assign a rating of 5 rather than 4 or 6.

If the descriptions for a given item occasionally do not seem to apply to the session you are rating, feel free to disregard them and use the more general scale below:

0	1	2	3	4	5	6
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

1. Agenda

Score	Rating (tick one box only)	Anchor points
0	☐	Therapist did not set an agenda
1	☐	
2	☐	Therapist set an agenda that was vague or incomplete
3	☐	
4	☐	Therapist worked with patient to set a mutually satisfactory agenda that included specific areas for discussion.
5	☐	
6	☐	Therapist worked with patient to set an appropriate agenda with specific and relevant areas for discussion suitable for the time available. Established priorities and then followed this agenda.

2. Feedback

Score	Rating (tick one box only)	Anchor points
0	☐	Therapist did not ask for feedback to determine patient's understanding of, or response to, the session.
1	☐	
2	☐	Therapist elicited some feedback from the patient, but did not ask enough questions to be sure the patient understood the therapist's line of reasoning during the session or to ascertain whether the patient was satisfied with the session
3	☐	
4	☐	Therapist asked enough questions to be sure that the patient understood the therapist's line of reasoning throughout the session and to determine the patient's reactions to the session. The therapists adjusted his/her behaviour in response to the feedback, when appropriate.
5	☐	
6	☐	Therapist was especially adept at eliciting and responding to verbal and non-verbal feedback throughout the session (e.g. elicited reactions to session, regularly checked for understanding, helped summarize main points at end of session).

3. Understanding

Score	Rating (tick one box only)	Anchor points
0	☐	Therapist repeatedly failed to understand what the patient explicitly said and thus consistently missed the point. Poor empathic skills.
1	☐	
2	☐	Therapist was usually able to reflect or rephrase what the patient explicitly said, but repeatedly failed to respond to more subtle communication. Limited ability to listen and empathize.
3	☐	
4	☐	Therapist generally seemed to grasp the patient's "internal reality" as reflected by both what the patient explicitly said and what the patient communicated in more subtle ways. Good ability to listen and empathize
5	☐	
6	☐	Therapist seemed to understand the patient's "internal reality" thoroughly and was adept at communicating this understanding through appropriate verbal and non-verbal responses to the patient (e.g. the tones of the therapist's response conveyed a sympathetic understanding of the patient's "message")

4. Interpersonal effectiveness

Score	Rating (tick one box only)	Anchor points
0	☐	Therapist had poor interpersonal skills. Seemed hostile, demeaning, or in some other way destructive to the patient.
1	☐	
2	☐	Therapist did not seem destructive, but had significant interpersonal problems. At times, therapist appeared unnecessarily impatient, aloof, insincere **or** had difficulty conveying confidence and competence.
3	☐	
4	☐	Therapist displayed a **satisfactory** degree of warmth, concern, confidence, genuineness, and professionalism. No significant interpersonal problems.
5	☐	
6	☐	Therapist displayed **optimal** levels of warmth, concern, confidence, genuineness, and professionalism, appropriate for this particular patient in this session.

5. Collaboration

Score	Rating (tick one box only)	Anchor points
0	☐	Therapist did not attempt to set up collaboration with patient.
1	☐	
2	☐	Therapist attempted to collaborate with patient, but had difficulty **either** defining a problem that the patient considered important **or** establishing rapport.
3	☐	
4	☐	Therapist was able to collaborate with patient, focus on a problem that both patient and therapist considered important, and establish rapport.
5	☐	
6	☐	Collaboration seemed excellent; therapist encouraged patient as much as possible to take an active role during the session (e.g. by offering choices) so they could function as a "team".

6. Pacing and efficient use of time

Score	Rating (tick one box only)	Anchor points
0	☐	Therapist made no attempt to structure therapy time. Session seemed aimless.
1	☐	
2	☐	Session had some direction, but the therapist had significant problems with structuring or pacing (e.g., too little structure, inflexible about structure, too slowly paced, too rapidly paced).
3	☐	
4	☐	Therapist was reasonably successful at using time efficiently. Therapist maintained appropriate control over flow of discussion and pacing
5	☐	
6	☐	Therapist used time efficiently by tactfully limiting peripheral and unproductive discussion and by pacing the session as rapidly as was appropriate for the patient.

7. Guided discovery

Score	Rating (tick one box only)	Anchor points
0	☐	Therapist relied primarily on debate, persuasion, or "lecturing". Therapist seemed to be "cross-examining" patient, putting the patient on the defensive, or forcing his/her point of view on the patient.
1	☐	
2	☐	Therapist relied too heavily on persuasion and debate, rather than guided discovery. However, therapist's style was supportive enough that patient did not seem to feel attacked or defensive.
3	☐	
4	☐	Therapist, for the most part, helped patient see new perspective through guided discovery (e.g., examining evidence, considering alternative, weighing advantages and disadvantages) rather than through debate. Used questioning appropriately.
5	☐	
6	☐	Therapist was especially adept at using guided discovery during the session to explore problems and help patient draw his/her own conclusions. Achieved an excellent balance between skilful questioning and other modes of intervention

8. Strategy for change *(Note: For this item, focus on the quality of the therapist's strategy for change, not on how effectively the strategy was implemented or whether change actually occurred.)*

Score	Rating (tick one box only)	Anchor points
0	☐	Therapist did not select compliance therapy techniques.
1	☐	
2	☐	Therapist selected compliance therapy techniques; however, either the overall strategy for bringing about change seemed vague **or** did not seem promising in helping the patient.
3	☐	
4	☐	Therapist seemed to have a generally coherent strategy for change that showed reasonable promise and incorporated compliance therapy techniques.
5	☐	
6	☐	Therapist followed a consistent strategy for change that seemed very promising and incorporated the most appropriate compliance therapy techniques.

9. Application of compliance therapy/medication management techniques *(Note: For this item, focus on how skillfully the techniques were applied, not on how appropriate they were or whether change actually occurred).*

Score	Rating (tick one box only)	Anchor points
0	☐	Therapist did not apply any compliance therapy or medication management techniques.
1	☐	
2	☐	Therapist used compliance therapy or medication management techniques, but there were **significant flaws** in the way they were applied.
3	☐	
4	☐	Therapist applied compliance therapy or medication management techniques **with moderate skill.**
5	☐	
6	☐	Therapist **very skillfully** and resourcefully employed compliance therapy techniques.

10. How would you rate the clinician in this session

0	1	2	3	4	5	6
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

Total score (add items 1-10 together)

Role play test

You will enter a room where you will be introduced to a patient who wants to discuss medication with you. They are concerned about the side effects they are experiencing from the antipsychotic medication they are taking (sulpiride and procyclidine) and have decided to stop taking it. You know from the notes that this is has happened before and that when they stop they quickly become unwell again. In the past they have responded well to medication that has got rid of very distressing voices and thoughts.

You have up to fifteen minutes to talk to the patient about their concerns. If you have not finished the interview within fifteen minutes you will be stopped.

The interview is being video-taped and will be rated by an independent rater. It will be destroyed at the end of the trial and will not be used for teaching or any other purpose without your expressed permission in writing.

KNOWLEDGE ABOUT MEDICATION MANAGEMENT QUESTIONNIARE (KAMMQ)

Please answer each question on the work sheet by placing a ☒ against the answer that you think is correct. Each question has only one correct answer. If you change your mind draw a line through the incorrect answer and place a 0 against your new answer. Please answer all the questions on the work sheet. Any questions that are unanswered will be scored as incorrect.

PATIENT PROFILE ONE

John is 38. He was diagnosed as suffering from schizophrenia 10 years ago. He has been prescribed various antipsychotics over the years with limited effect and is currently maintained on zuclopenthixol decanoate, administered every two weeks. He has only partially responded to this drug and continues to complain of hallucinations and has marked negative symptoms.

1. John is receiving zuclopenthixol decanoate that is a conventional antipsychotic. Which of the following best describes how these drugs work to relieve psychotic symptoms?

A. Block dopamine receptors ☐
B. Block serotonin receptors ☐
C. Block histamine receptors ☐
D. Inhibit the reuptake of dopamine ☐
E. Inhibit the reuptake or serotonin ☐

2. Conventional antipsychotics are most effective in treating

A. Positive symptoms ☐
B. Negative symptoms ☐
C. Cognitive functioning ☐
D. Extrapyramidal symptoms ☐
E. Affective symptoms ☐

3. Like John, many patients with schizophrenia do not respond to conventional antipsychotics. What proportion of patients **do not** respond to these drugs?

A. Approximately 80% ☐
B. Approximately 50% ☐
C. Approximately 20% ☐
D. Approximately 100% ☐
E. Approximately 10% ☐

4. Conventional antipsychotics are associated with extrapyramidal symptoms (EPS). Which of the following group of side-effects are commonly known as EPS?

A. Tardive dyskinesia, agranulocytosis, neuroleptic malignant syndrome, dystonias ☐
B. Akathisia, tardive dyskinesia, agranulocytosis, parkinsonism ☐
C. Neuroleptic malignant syndrome. Dystonias, tardive dyskinesia, akathisia ☐
D. Dystonias, parkinsonism, akathisia, tardive dyskinesia ☐
E. Parkinsonism, tardive dyskinesia, agranulocytosis, dystonias ☐

5. Sexual dysfunction is a common side effect of antipsychotics why do patients experience these symptoms?

A. Increased levels of serotonin ☐
B. Raised levels of prolactin ☐
C. Blockade of histamine receptors ☐
D. Hyperdopaminergia ☐
E. Increased levels of GABA ☐

6. Clozapine belongs to the group of drugs termed atypical antipsychotics. What is one of the major characteristics of an atypical drug?

A. Blockade of adrenergic receptors ☐
B. Efficacy in improving cognitive functioning ☐
C. It's new ☐
D. It's expensive ☐
E. It does not induce EPS at therapeutic doses ☐

7. Clozapine has been shown to be effective for other patients like Mr. Smith who do not respond to conventional antipsychotics. What proportion of treatment-resistant patients respond to clozapine?

A. 80%-90% ☐
B. 30%-60% ☐
C. 10%-20% ☐
D. 50%-90% ☐
E. 5%-10% ☐

8. Novel antpsychotics (excluding clozapine) have been shown to be as effective as conventional drugs in a number of ways. In which of the following are novel antipsychotics no different to conventional treatments?

A. Inducing EPS ☐
B. Reducing negative symptoms ☐
C. Enhancing cognitive function ☐
D. Treating positive symptoms ☐
E. Reducing affective symptoms ☐

PATIENT PROFILE TWO
Mary has had a diagnosis of schizophrenia for six years. She has had several relapses requiring hospitalisation as she tended to stop taking her medication when discharged. Mary says the medication makes her feel worse and her reason for smoking cannabis is to ease the side effects.

9. How common is non-compliance in patients treated with antipsychotic medication?

A. Around 10% ☐
B. Around 90% ☐
C. Around 50% ☐
D. Around 20% ☐
E. Around 70% ☐

10. Mary says the medication makes her feel worse and may be experiencing a negative subjective response. What is the term used to describe this response?

A. Euphoric ☐
B. Dysphoric ☐
C. Manic ☐
D. Unfavourable ☐
E. Panic ☐

11. Mary complains of blurred vision and urinary retention. To which group of side effects do these belong?

A. EPS ☐
B. Neurological ☐
C. Anticholinergic ☐
D. Toxic ☐
E. Photosensitivity ☐

12. Mary would be considered to have a dual diagnosis of schizophrenia and substance misuse. What proportion of patients with a diagnosis of schizophrenia are reported to have a dual diagnosis in urban areas of the UK?

A. Approximately 10% ☐
B. Approximately 85% ☐
C. Approximately 35% ☐
D. Approximately 20% ☐
E. Approximately 5% ☐

13. Mary's poor compliance may be related to her lack of insight (awareness of illness). Which of the following has ***not*** been shown to affect compliance?

A. Extrapyramidal symptoms ☐
B. Complex treatment regimes ☐
C. Lack of knowledge about medication ☐
D. Substance misuse ☐
E. Grandiose delusions ☐

14. Mary may benefit from compliance therapy. What are the components of this approach?

A. Cognitive behavioural therapy and psychoeducation ☐
B. Psychoeducation and behaviour therapy ☐
C. Motivational interviewing and psychoeducation ☐
D. Cognitive behaviour therapy and motivational interviewing ☐
E. Psychodynamic psychotherapy and motivational interviewing ☐

15. What is one of the key principles of compliance therapy?

A. Confronting patients beliefs about medication ☐
B. Collaborating with patients on decisions about medication ☐
C. Encouraging the patient to stop medication ☐
D. Coercing the patient into taking medication ☐
E. Presenting information to patients using didactic methods. ☐

16. Mary has a very negative view of treatment and this may affect her long-term compliance. How might you assess these views?

A. Use the KGV ☐
B. Use the Barnes scale ☐
C. Use the DAI-30 ☐
D. Use the LUNSERS ☐
E. Use the SFS ☐

Medication management course evaluation

For each of the key components of the course please state: 1. How satisfied you were with way in which it was taught; 2. How relevant it was to your clinical practice; 3. Whether you have been able to apply what you have learnt in practice.

1. Assessing symptoms

Satisfaction with how the component was taught

1. Satisfied ☐
2. Neither satisfied or dissatisfied ☐
3. Dissatisfied ☐

Relevance to clinical practice

1. Relevant ☐
2. Neither relevant or irrelevant ☐
3. Irrelevant ☐

Have you been able to apply what you have learnt in practice?

1. Completely ☐
2. Partially ☐
3. Not at all ☐

2. Assessing factors affecting compliance

Satisfaction with how the component was taught

1. Satisfied ☐
2. Neither satisfied or dissatisfied ☐
3. Dissatisfied ☐

Relevance to clinical practice

1. Relevant ☐
2. Neither relevant or irrelevant ☐
3. Irrelevant ☐

Have you been able to apply what you have learnt in practice?

1. Completely ☐
2. Partially ☐
3. Not at all ☐

4. Psychopharmacology

Satisfaction with how the component was taught
1. Satisfied ☐
2. Neither satisfied or dissatisfied ☐
3. Dissatisfied ☐

Relevance to clinical practice
1. Relevant ☐
2. Neither relevant or irrelevant ☐
3. Irrelevant ☐

Have you been able to apply what you have learnt in practice?
1. Completely ☐
2. Partially ☐
3. Not at all ☐

4. Clinical supervision

Satisfaction with how the component was taught
1. Satisfied ☐
2. Neither satisfied or dissatisfied ☐
3. Dissatisfied ☐

Relevance to clinical practice
1. Relevant ☐
2. Neither relevant or irrelevant ☐
3. Irrelevant ☐

Have you been able to apply what you have learnt in practice?
1. Completely ☐
2. Partially ☐
3. Not at all ☐

4. Medication management key skills role play

Satisfaction with how the component was taught
1. Satisfied ☐
2. Neither satisfied or dissatisfied ☐
3. Dissatisfied ☐

Relevance to clinical practice
1. Relevant ☐
2. Neither relevant or irrelevant ☐
3. Irrelevant ☐

Have you been able to apply what you have learnt in practice?

1. Completely ☐
2. Partially ☐
3. Not at all ☐

4. The medication management course overall

Satisfaction with how the component was taught

1. Satisfied ☐
2. Neither satisfied or dissatisfied ☐
3. Dissatisfied ☐

Relevance to clinical practice

1. Relevant ☐
2. Neither relevant or irrelevant ☐
3. Irrelevant ☐

Have you been able to apply what you have learnt in practice?

1. Completely ☐
2. Partially ☐
3. Not at all ☐

RANDOMISATION SEQUENCES

Bland M. (1994) *An introduction to medical statistics.* Oxford medical publications, Oxford

1	36	45	88	3	1	28	73	59	43	46	32
32	67	15	32	49	54	55	75	17	2	90	59
66	18	46	95	54	65	89	16	80	95	33	15
18	60	56	46	3	98	41	90	22	48	37	80
1	91	39	33	80	40	82	38	26	20	39	71
4	55	25	71	27	14	68	04	99	24	82	73
43	92	68	18	99	47	54	5	02	99	10	75
77	21	88	55	79	97	70	32	59	87	75	35
62	53	6	79	85	55	66	63	84	08	63	04
18	34	53	94	58	01	55	05	90	99	7	33
53	95	28	06	81	34	95	13	93	37	16	95
06	15	91	89	99	37	16	8	74	75	13	13
22	16	7	76	15	57	42	38	96	23	90	24
58	26	71	46	9	06	66	30	43	00	66	2
60	36	60	46	05	17	31	66	80	91	01	62
35	10	92	83	31	60	87	30	6	83	17	85
31	48	13	23	17	32	68	14	84	96	1	1
61	21	31	49	98	29	7	70	72	1	1	35
23	69	47	14	27	14	74	52	35	12	27	82
01	01	74	41	8	77	53	68	53	26	55	16
35	66	31	87	82	09	13	61	05	50	10	94
85	6	32	10	72	95	67	88	21	72	09	48
73	03	97	14	1	1	57	85	67	94	91	48
35	49	39	41	80	17	54	45	23	66	82	60
15	15	16	08	90	92	86	3	32	26	01	20
02	72	45	94	74	97	19	99	46	16	22	09
29	66	15	44	74	94	92	48	13	75	85	81
28	95	41	36	30	17	69	13	53	55	35	87
43	23	83	32	79	40	92	20	83	76	82	61
24	20	18	08	29	79	37	00	33	34	86	55
10	91	18	86	43	50	67	79	33	58	19	37
29	99	85	55	63	66	71	98	85	20	3	1
93	63	91	77	21	99	62	20	65	1	1	14
04	88	86	28	92	04	03	42	99	87	08	20
30	53	82	24	21	66	22	81	58	30	80	21
10	15	53	26	90	33	77	51	19	17	49	27
14	22	37	21	77	13	69	3	1	20	22	67
29	75	32	69	79	37	23	32	43	23	5	1

RANDOM PERMUTED BLOCKS

E = experimental group; C = control group

EECC EECC CECE CECE

APPENDIX 9

Breakdown of costs

Estimated cost of providing one medication management course to train 12 CPNs

Trainer (twelve days)	£ 1,384
University overheads	£ 1,798
Photocopying	£ 400
Videotape	£ 30
Prescribing guidelines	£ 180
CPN replacement costs*	£13,896
Total cost of training	**£17,688**

Cost per CPN £1,474

APPENDIX 10

INSTITUTE OF PSYCHIATRY

Medication management project

Patient information sheet

We would like to invite you to participate in a research study. We are interested to find out whether we can improve your care by giving extra training to your community psychiatric nurse (CPN) on various aspects of your treatment, especially medication. All we ask of you is that you complete some questionnaires and be interviewed by a researcher now, after about six months and again after 12 months. The questionnaires will take approximately half an hour and cover how you are managing, how you are feeling and how the medication suits you. The interview will take approximately 40 minutes. If you do not wish to participate or if you do but then change your mind, this will not affect you treatment or care in any way.

If you have any concerns about the study contact:

RICHARD GRAY
Tutor-Practitioner
T: 0171 919 139

INSTITUTE OF PSYCHIATRY

Medication management project

Consent form

Patients name _____ Patient ID code _____

1. I voluntarily agree to take part in the study.
2. I am over 18 years of age.
3. I have been given a full explanation of the purpose of the study.
4. I am aware of what is expected of me by agreeing to participate in this study.
5. I am aware that I can refuse to participate in this study and that by not agreeing to take part my care and treatment will not be affected in any way.
6. I understand that I can withdraw my consent from the study at any time.
7. I understand that I will not be referred to by name in any report concerning this study.

Signature of patient	Signature of witness
Signed _____	Signed _____
Date _____	Date _____

Patient demographic information

Patients name _____

Date of assessment _____

Age (in years) _____

Gender
1. Male ☐
2. Female ☐

Ethnicity
1. White ☐
2. Black ☐
3. Asian ☐
4. Other ☐ (specify) _____

Duration of illness (in years) _____

Age at onset of illness (in years) _____

Number of previous psychiatric admissions _____

Number of detentions under MHA _____

Time since last admission (in months) _____

Diagnosis _____

Smoking status _____

Alcohol status _____

CPA status _____

Marital status _____

Employment status _____

PRESCRIBING INFORMATION

Drug one

Name _____

Daily dose _____

Drug two

Name _____

Daily dose _____

Drug three

Name _____

Daily dose _____

Drug four

Name _____

Daily dose _____

Drug five

Name _____

Daily dose _____

Psychological treatments (e.g. CBT, family work)

_____

_____

_____

_____

_____

Inpatient bed days

Week 26 assessment

Since the last assessment how many days has the patient spent in psychiatric hospital.

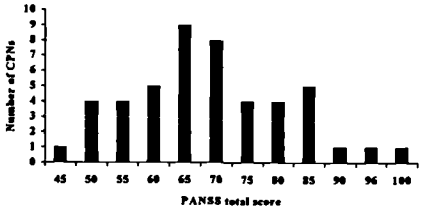
_____ days

Week 52 assessment

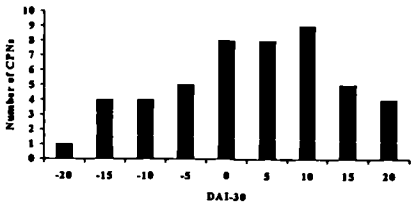
Since the last assessment how many days has the patient spent in psychiatric hospital?

_____ days

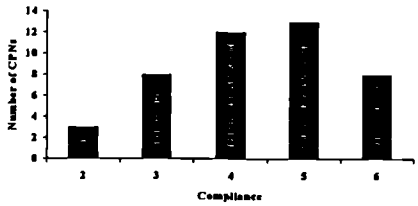
Histogram - PANSS-total



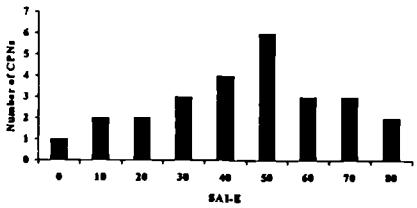
Histogram - DAI-30



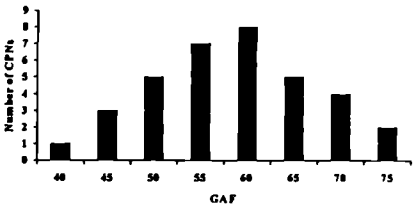
Histogram - Compliance



Histogram - SAI-E



Histogram - GAF



Trainee satisfaction with training

Course component: assessing symptoms n=44					
Satisfaction with how the component was taught		Relevance to clinical practice		Ability to apply in practice	
Satisfied	37 (84%)	Relevant	32 (73%)	Completely	29 (66%)
Neither satisfied or dissatisfied	7 (16%)	Neither relevant or irrelevant	12 (27%)	Partially	15 (44%)
Dissatisfied	0 (0%)	Irrelevant	0 (0%)	Not at all	0 (0%)
Course component: assessing factors affecting compliance n=44					
Satisfaction with how the component was taught		Relevance to clinical practice		Ability to apply in practice	
Satisfied	35 (80%)	Relevant	34 (77%)	Completely	34 (77%)
Neither satisfied or dissatisfied	9 (20%)	Neither relevant or irrelevant	10 (23%)	Partially	11 (23%)
Dissatisfied	0 (0%)	Irrelevant	0 (0%)	Not at all	0 (0%)
Course component: psychopharmacology n=44					
Satisfaction with how the component was taught		Relevance to clinical practice		Ability to apply in practice	
Satisfied	43 (98%)	Relevant	44 (100%)	Completely	27 (61%)
Neither satisfied or dissatisfied	1 (2%)	Neither relevant or irrelevant	0 (0%)	Partially	17 (39%)
Dissatisfied	0 (0%)	Irrelevant	0 (0%)	Not at all	0 (0%)

Course component: clinical supervision n=44					
Satisfaction with how the component was taught		Relevance to clinical practice		Ability to apply in practice	
Satisfied	31 (70%)	Relevant	29 (66%)	Completely	24 (55%)
Neither satisfied or dissatisfied	13 (30%)	Neither relevant or irrelevant	15 (34%)	Partially	20 (45%)
Dissatisfied	0 (0%)	Irrelevant	0 (0%)	Not at all	0 (0%)
Course component: medication management key skills role play n=44					
Satisfaction with how the component was taught		Relevance to clinical practice		Ability to apply in practice	
Satisfied	26 (59%)	Relevant	31 (70%)	Completely	23 (52%)
Neither satisfied or dissatisfied	18 (41%)	Neither relevant or irrelevant	13 (30%)	Partially	21 (48%)
Dissatisfied	0 (0%)	Irrelevant	0 (0%)	Not at all	0 (0%)
Course overall n=44					
Satisfaction with how the component was taught		Relevance to clinical practice		Ability to apply in practice	
Satisfied	40 (90%)	Relevant	37 (84%)	Completely	28 (64%)
Neither satisfied or dissatisfied	4 (10%)	Neither relevant or irrelevant	7 (6%)	Partially	16 (36%)
Dissatisfied	0 (0%)	Irrelevant	0 (0%)	Not at all	0 (0%)

PUBLICATION LIST

Gray R. Wykes T. Parr A-M. (in press) The use of outcome measures to evaluate the efficacy and tolerability of antipsychotic medication: A comparison of Thorn graduate and CPN practice. *Journal of Psychiatric and Mental Health Nursing*

MAJOR CONFERENCE PRESENTATIONS

Gray R. A randomised controlled trial of medication management training for CPNs. Presented at the third psychological treatments for schizophrenia conference 24th and 25th September 1999